A PROSPECTIVE OPEN LABELLED PHASE-II NON-RANDOMIZED CLINICAL TRIAL ON HERBAL FORMULATION OF "NERUNJI VER KUDINEER" FOR THE TREATMENT OF "KALLADAIPPU" (UROLITHIASIS)

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BONAFIDE CERTIFICATE

This is to certify that the dissertation entitled **"A Prospective Open Labelled Phase-II Non-Randomized Clinical Trial On "NERUNJI VER KUDINEER" for "KALLADAIPPU" (UROLITHIASIS)** is a bonafide work done by **Dr.P.BERNATH (Reg. No.321611002)** Govt. Siddha Medical College, Palayamkottai - 627002 in partial fulfilment of the university rules and regulations for award for **MD (S) POTHU MARUTHUVAM (BRANCH-I**) under the guidance of Dr.S.Justus Antony M.D(S). and supervision of Prof.Dr.A.Manoharan M.D(S).(Ph.D) ,during the academic year of **2016-2019.**

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DECLARATION

I declare that the dissertation entitled **"A Prospective Open Labelled Phase-II Non- Randomized Clinical Trial on "NERUNJI VER KUDINEER" for "KALLADAIPPU" (UROLITHIASIS)** submitted for the degree of MD Siddha Medicine of Government Siddha Medical College, Palayamkottai, Tirunelveli, Tamil Nadu (The Tamil Nadu Dr. M.G.R. Medical University, Chennai) the record of work carried out by me under the guidance of **Dr.S.Justus Antony M.D(S).,** Grade II Lecturer, Department of Pothu Maruthuvam, Govt. Siddha Medical College, Palayamkottai, and under the supervision of **Prof.Dr.A.Manoharan,MD (S), (Ph.D).,** Head of the department, Department of Pothu Maruthuvam, Govt. Siddha Medical College, Palayamkottai. This work has not formed the basis of award of any degree, diploma, associates fellowship or other titles in this university or any other university or institution of higher learning.

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CONTENTS

LIST OF TABLES

LIST OF ABBREVATIONS

%	-	Percentage
WBC	-	White Blood Corpuscles
DC	-	Differential Count
ESR	-	Erythrocyte Sedimentation Rate
Hb	-	Haemoglobin
P	-	Polymorphs
L	-	Lymphocytes
E	-	Eosinophils
BFT	-	Before Treatment
AFT	-	After Treatment
Alb	-	Albumin
Epi.Cells	-	Epithelial Cells
RBCS	-	Red Blood Corpuscles
NAD	-	No Abnormal Deposits
mm	-	Millimeter
ATP	-	Adenosine tri Phosphate
dl	-	Decilitre
MRI	-	Magnetic Resonance Imaging
CT	-	Computed Tomography
NVK	-	Nerunji Ver Kudineer

ABSTRACT

KALLADAIPPU is the most common disease in our country. The evidence of the disease *KALLADAIPPU* was derived from *YUGI VAIDHIYA CHINTHAMANI* 800, by Dr.K.Anbarasu B.S.M.S (Page.No.283). The clinical features of *KALLADAIPPU* can be correlated with *UROLITHIASIS* in modern science. Urolithiasis is a term originated from three Greek words "ouron" for urine, "oros" for flow, and "lithos" for stone. It is the formation of calculi which are formed or located anywhere in the urinary system (i.e. kidneys, bladder, urethrae, and urinary tract).

Many herbal and herbal-mineral formulations have been described in Siddha text books. One such drug ***NERUNJI VER KUDINEER*** *m*entioned in the book of ***AATHMARATCHAMIRTHAM ENNUM VAIDHYA SARASANGIRAGAM*** (Page.no:349). A total of 40 patients of both sex (20 OPD and 20 IPD) were selected and administered with the clinical trial medicine "***NERUNJI VER KUDINEER***" 100 ml BID at PG Department of Pothu Maruthuvam, Govt. Siddha Medical College and Hospital, Palayamkottai. The whole study period is between August 2018 and June 2019.

The clinical trial medicine was subjected to Biochemical, Toxicity and Pharmacological studies. In clinical study 75% of out patients and 50% of In patients showed Good response. And 25% of Out patients and 45% In patients showed Moderate response. Poor response in 5% of IPD. No Adverse reaction was found in this clinical study. The statistical analysis showed good significant value ($P<0.0001$). The ***Nerunji ver Kudineer*** is safe and effective and affordable cost in the treatment of Kalladaippu Noi (Urolithiasis).

CHAPTER-I

INTRODUCTION

The Siddha system is one of the oldest systems of medicine in India.The term siddha means achievements and Siddhars were saintly persons who achieved results in medicine. The siddha system is largely therapeutic in nature.The word Siddha comes from the tamil word Siddhi which means perfection.According to popular belief, the siddha system of medicine is divine in origin. Siddhars were spiritual masters who possessed the siddhis or unique powers. The basic theory of Siddha system of medicine is "Food is medicine, Medicine is food".According to the siddha medicine system diet and lifestyle play a major role in health and curing diseases.

According to Siddha system, siddhars defined 96 principles as the constituents of the human being. In that PANCHABOOTHAM are the basic elements which are included as first section of 96 thathuvams in each and every bit of all the physical and subtle bodies i.e the human body and the universe. They are Aagayam (space), Kaal (air), Thee (fire), Neer(water), Mann(earth).The physiological function of the human body is mediated by VATHAM, PITHAM, KAPAM i.e three Uyir Thathukal formed by the combination of five basic elements.When the normal equilibrium of the three humors vatham,pitham and kapam were disturbed disease is caused.

The first phase in human life is attributed to vatham, the middle phase to pitham, and the last phase to kapam. Thus the three humours are said to occupy the lower, middle and upper parts of the body respectively and maintain their integrity and function. The Siddha medicine has been claimed to revitalize and rejuvenate the metabolic dysfunctions in organs that cause the disease and maintains the bio-regulating factors namely Vatham, Pitham, Kapam. The seven physical constituents UDAL THATHUKAL such as Saaram(plasma), Seneer(blood), Oon(muscle), Kozhuppu(adipose tissue), Enbu (bone), Moolai(bone marrow), Sukkilam(semen).

In ***yugi vaidhiya chinthamani***- 800, urological disorders are classified into two categories such as

1) Neerinai perukkal noi – where the urination will be excess .
2) Neerinai arukkal noi – where the urine output will be reduced .

The disease KALLADAIPPU is placed under Neerinai Arukkal noi. One of the works of yugi munivar, Kalladaippu is dealt under the chapter **KALLADAIPPU**

ROGAM NITHANAM. Yugi documented the sequential order of dissemination of knowledge of Kalladaippu from lord shiva to till yugi for the benefit of the people living in the world.

Urolithiasis is the process of forming stones in the kidneys, bladder, and or urethra. It is the most common disease of present society due to modern life style, abnormal diet habits, and low fluid intake. Most stones formed due to a combination of genetic and environmental factors. The diagnosis of calculi can be confirmed by ultra sound examination, urine & blood test are also commonly performed.

Several drugs and medicines are available for treating KALLADAIPPU NOI. However, clinical trials on the treatment of Kalladaippu noi have not yet been undertaken the medicine "***NERUNJI VER KUDINEER***" (Internal), it has to mention ***AATHMARATCHAMIRTHAM ENNUM VAIDHYA SARASANGIRAGAM*** (Pg.no.349) text book. It is well known for its diuretic and lithotriptic action in treating the disease KALLADAIPPU.

CHAPTER - II

2.1 AIM AND OBJECTIVES

AIM :

A prospective open labelled phase-II non-randomized clinical study about ***NERUNJI VER KUDINEER*** in the management of ***KALLADAIPPU NOI*** (urolithiasis).

OBJECTIVES:

A.PRIMARY OBJECTIVE

To evaluate the therapeutic efficacy of clinical trial drug in Kalldaippu.

B.SECONDARY OBJECTIVE:

1. To collect the various literary evidence for Kalladaippu disease.
2. To study the Siddha formulation of the drug NERUNJI VER KUDINEEER in the treatment of KALLADAIPPU (UROLITHIASIS) for the clearance / reduction in the size of the calculus and clinical symptoms.
3. To collect about the disease Kalladaippu noi with deep observation of aetiology, clinical features mentioned in various Siddha literatures and also in modern text books, diagnosis and prognosis.
4. To confirm the diagnosis in Siddha system with the help of modern parameters during and after treatment in some patients.
5. To perform urine analysis, Haematological studies and ultrasonography.
6. 6. To determine Biochemical , Microbial analysis of the clinical trial drug.
7. To evaluate pharmacological activity of my trial drug ***NERUNJI VER KUDINEER***.
8. To assess the safety profile of the clinical trial drug.

CHAPTER-III
REVIEW LITERATURE

3.1 IN JOURNAL REVIEW OF DRUG

Nerunji ver kudineer is a siddha polyherbal formulation consists of Nerunji ver, Sirupeelai ver, Sirukeerai ver and Seeragam.

NERUNJI VER: (Tribulus terrestris.L)

Taxonomy (plants.usda.gov)

Kingdom	**:**	plantae-
Subkingdom	**:**	Tracheobionta
Superdivision	**:**	Spermatophyta
Division	**:**	Magnoliophyta
Class	**:**	Dicotyledons
Subclass	**:**	Rosidae
Order	**:**	Sapindales
Family	**:**	Zygophyllaceae
Genus	**:**	Tribulus L. –Puncturevine
Species	**:**	***Tribulus terrestris L.*** –Puncturevine

FIG.3.1.A. ***NERUNJI VER***

Tribulus terrestris is an annual herb which belongs to the Zygophyllaceae family.It is a taprooted herbaceous perennial plant that grows as a summer annual in colder climates.The stems radiate from the crown to a diameter of about 10cm to over 1m often branching.The are usually prostrate ,grow upward in shade or among taller plants.Leaves are opposite and pinnately compound. The flowers are five lemon-yellow petals.The nutlets are hard and bear two to four sharp spines. This plant has been used in traditional medicine for the treatment of various diseases for hundreds of decades***. Saurabh chhatre et al (2014) was studies the main active phytoconstituents of this plant include flavonoids, alkaloids, saponins, lignin, amides, and glycosides. The plant parts have different pharmacological activities including aphrodisiac, antiinflammatory, antimicrobial and antioxidant potential. T. terrestris is most often used for infertility and loss of libido. It has potential application as immunomodulatory, hepatoprotective, hypolipidemic, anthelmintic and anticarcinogenic activities.***

SIRUPEELAI VER: (*Aerva lanata.L)*

Taxonomy: (plants.usda.gov)

Kingdom	**:** Plantae
Subkingdom	**:** Tracheobionta
Superdivision	**:** Spertophyta
Division	**:** Magnoliphyta
Class	**:** Dicotyledons
Subclass	**:** Caryophyllidae
Order	**:** Caryophyllales
Family	**:** Amaranthaceae
Genus	**:** Aerva Forssk- aerva
Species	***: Aerva lanata L.***

FIG.3.1.B.SIRUPEELAI VER

FIG.3.1.C.SIRUPEELAI

Extensive research from the last decades has revealed the applications of *Aerva lanata* (Linn) for the treatment of urinary disorders. It is a natural plant belonging to the family Amaranthaceae and grows in the warmer parts of India ascending to 1000 m.The root has a camphor like aroma. The dried flowers which look like soft spikes. It is commonly known as sirupeelai in Tamil or Siddha.The plant is extensively used in urinary dysfunctions such as Ashmari (urinary calculi), Mootrakrichra (dysuria), and Mootravikara by most of the Ayurveda and Siddha practitioners in South India, in the name of pashanabheda. The plant bears almost all the characteristics similar to that of the source of pashanabheda. ***The primary phytoconstituents reported from this plant are flavonoids, tannins, anthraquinones, alkaloid, phenol, proteins, amino acids, and carbohydrates.In the traditional medicine of India the juice of crushed Aerva lanata root is used for jaundice therapy. Manoj Goyal et al (2001) was studies reported diuretic, anti-inflammatory, hypoglycemic, anti-diabetic, anti-parasitic, antimicrobial, hepatoprotective, anti-urolithiasis, antiasthmatic, antifertility and hypolipidemic properties of Aerva lanata***.

SIRUKEERAI VER*:(Amaranthus tricolor.L)*

FIG.3.1.D.SIRUKEERAI VER

Taxonomy (plants.usda.gov)

Kingdom **:** Plantae –Plants

Subkingdom **:** Tracheobionta

Superdivision **:** Spermatophyta

Division **:** Magnoliophyta

Class **:** Dicotyledons

Subclass **:** Caryophyllidae

Order **:** Caryophyllales

Family **:** Amaranthaceae – Amaranth Family

Genus **:** Amaranthus L.-pigweed

Species **:** ***Amaranthus tricolor*** **L**. – Joseph`s-coat

Amaranthus plants are annual or short lived perennial plants. Catkin- like cymes of densely packed flowers grows in summer or autumn. Amaranthus plants or spinach, are used as food sources worldwide. Amaranthus leaves are rich in antioxidant compounds, which act as free radical scavengers. Oxidative stress caused by the aberrant production of reactive oxygen species (ROS) represents an important mechanism for neuronal dysfunction and cell loss in different neurodegenerative disorders. ***The neuroprotective effects of antioxidant-containing plants have been extensively demonstrated in different models of neurotoxicity. However, few studies have investigated the antioxidant properties of Amaranthus extracts and their effect on the nervous system. A. tricolor extracts can significantly decrease cell toxicity and intracellular ROS production in SH-SY5Y cells. Interestingly, the extracts also significantly downregulated the expression of oxidative stress genes such as HMOX-1, RAGE, and RelA/ NF-κB. Amaranthus leaves may be useful for reducing oxidative stress and may be beneficial for age-related diseases and neurodegenerative disorders. (https://plants.jstor.org).***

SEERAGAM (*Cuminum cyminum.L)*

Taxonomy (plants.usda.gov)

Kingdom	**:**	Plantae – Plants
Subkingdom	**:**	Tracheobionta
Superdivision	**:**	Sprematophyta
Division	**:**	Magnoliophyta
Class	**:**	Dicotyledons
Subclass	**:**	Rosidae
Order	**:**	Apiales
Family	**:**	Apiaceae – Carrot Family
Genus	**:**	Cuminum L. – cumin
Species	**:**	***Cuminum cyminum* L.** - Cumin

FIG.3.1.E.SEERAGAM

Cuminum cyminum*,** which is a popular spice that is used as a flavoring agent, is widely used in food. The cumin seeds ***Cuminum cyminum* L.** belong to the family Apiaceae and are consumed in large quantities by Indians.The cumin plant grows to 30-50cm tall and is harvested by hand.It is an annual herb with a slender, glabrous,branched stem.The leaves are pinnate or bipinnate with thread-like leaflets. The flowers are small white or pink and borne in umbels. The fruit is a lateral fusiform or ovoid achene 4-5 mm long, containg two mericarpes with a single seed. ***R.K. Johri et al (2011) was studies Cumin is widely used in medicine for the treatment of dyspepsia, diarrhea, and jaundice, as it has stomachic, diuretic, carminative, and antispasmodic properties . China is an important exporter of this commodity and also uses it in traditional medicine. The use of natural antimicrobial compounds is important in the control of human and plant diseases of microbial origin, Many natural compounds have been identified that have antimicrobial activity, including essential oils .

3.2. GUNAPADAM ASPECT OF DRUGS:

Serial No	Tamil Name / Botanical Name	Part used	Suvai	Thanmai	Pirivu	Action
1	*Nerunji ver/* ***Tribulus terrestris.L***	*Root*	**S**weet, Astringent	*Seetham*	*Sweet*	*Refrigerant,* ***Diuretic***
2	*Sirupeelai ver /* ***Aerva lanata.L***	*Root*	Bitter	*Veppam*	*Kaarppu*	***Diuretic, Lithotriptic***
3	*Sirukeerai ver /* ***Amaranthus tricolor.L***	*Root*	Sweet	*Thatppam*	*Sweet*	*Stomachic, Febrifuge*
4	*Seeragam /* ***Cuminum cyminum. L***	*Fruits*	Sweet, *Kaarppu*	*Thatppam*	*Sweet*	*Carminative, Stimulant, Astringent*

3.3. SIDDHA ASPECT OF KALLADAIPPU:

Siddha system of medicine is an old age traditional system with unique properties is not only treating a disease but gives us an immense perception and approach to lead a healthy life. Among the various diseases, "Kalladaippu Noi" is one of the most common diseases. Several preventive and causative treatments are found in various siddha literatures for Kallaidaippu Noigal. In Siddha literature, Kalladaippu noi is mentioned by Yugi Munivar in "*Yugi Vaidhya Chinthamani 800"*. It is one of the urinary diseases which come under Neerinai Arukkal Noigal.

"நீரிரு வினைக் குணத்தை
நீயறி விரித்துச் சொல்வோம்
நீரினை பெருக்கலொன்றே
நீரினை யருக்க லொன்றே
நீரிழிவுடனே கொல்லும்
நீர்க்கட்டு வினைகளொன்று"

-நோய்நாடல் நோய் முதல் நாடல் - 2ம் பாகம், பக்கம் 420

3.3.1.வேறுபெயர்கள் (SYNONYM)

Achamarirogam.

3.3.2 இயல் (DEFINITION)

a) In "Agathiyar Gunavagadam" , kalladaippu noi is defined as below:

"தானென்ற மூத்திரத்தில் நற நறவென்று
தங்கியதோர் பொடியெனும் மணல்தானப்பா
வானென்ற சிறியதொரு கல்லாவதப்பா
வளமாக வந்துவிழும் நோய்க்கு தானே
ஏனென்ற அஸ்மரி ரோகமென்ற பேராம்
எளிதாகக் கல்லுகள்தான் விழுகும்போது
கோனென்ற குண்டிக்காய் மூத்திரக்குழலப்பா
குணமான மூத்திரப்பை நீர்த்தாரைக் கேளே"
கேளடா முன் குறியில் எரிச்சல் கண்டு
கெடியாக வேதனைகள் காட்டுமப்பா
வாளடா சிறியதொரு கற்கள்தானே
வளமான மூத்திரப்பை குழல் வழிப்படியாய்த்
தேளடா வரும்போது திரேகந்தன்னில்
தெரிப்பது போல யிருவேதனை செய்யும்பாரு
நாளடா கற்கள்தா னிறங்கிவிட்டால்
நலமான வேதனைகள்தான் தீரும்பாரே"

அகத்தியர் குணவாகடம் பக்கம்.6

According to Agathiyar, Kalladaippu noi defines as "Deposition of crystals which look like sand followed by small size of stones which is excreted in the urine. Sometimes the stones obstruct in the kidney ureter, urinary bladder and urethra. When the stones reaching the uretheral orifice, intense burning sensation in the genital area. Then the stones get expelled and pain is relieved.

3.3.3 நோய் வரும் வழி (AETIOLOGY)

a) According to Maanmurugiyam are mentioned as,

கருநீரடக்கல் விரையில் அடிபடல்
நீரியந்தாக்கல் சிறு நீரடக்கல்
வளிநோய்மிருக்கு முணவும் ஒழுக்கமும்
கடைப்பிடித்திடுதல் மேகமுதற் பல
பிணியுறல் எழுமிவை யடிப்படையாகக்

கல்லடைப்புயென்னும் கடும்பிணி விளையும்
வளியது மீறியோடு மல்லாது
கருநீரொடுங் கலந்து நீரகத்துச்
சிறுநீர்க் கழீவு தொடுத்தாலும்
அன்னவை கல்லெனத் திரளுமென்ப
- மான்முருகியம் பக்கம்.118

The above poem described as,

- Trauma on testies, suppression of urine & semen
- Derangement of humour in blood.
- Excessive indulgence in sexual activity.
- Inflammation of bladder.
- Syphilis, stagnation of urine in urinary treat.
- Dryness of semen causes formation of stones.
- Increased intake of food that cause flatulence.

3.3.4 பொதுகுறி குணங்கள்(COMMON SYMPTOMS)

உந்தி தன்னினும் அதன் கீழ் மருங்கினும்
விரைநரம் பிடித்தும் நோவு தோன்றல்
சிறுநீர் நெறியில் கல்லுரத்தடுப்பின்
முரித்து முரித்து நீர் வீழ்ந்திடுதல்
கல்லது விலகி நின்றிடின் சிறுநீர்
தெளிந்தின மஞ்சள் நிறத்தி லொழுதல்
எனுமிவை கல்லடை பொதுகுறி யென்ப
நோய் நாடல் நோய்முதல் நாடல் பாகம் - 2 பக்கம் 427

- Gradual or sudden obstruction of flow of urine
- unbearable pain (i.e agonizing pain) in the penis
- Burning and scanty micturiation and Haematuria
- Colicky pain radiating from loin to groin region, lower abdomen, urethera & genitalia if the calculus is irregular in shape.

3.3.5 வகைகள்- (CLASSIFICATION)

A) In "Yugi vaidhya chinthamani 800"

"தோன்றிடதோர் நாலினிட நாமங்கே ளாய்
சுறுக்கான வாதத்தின் கல்ல டைப்பு

பூன்றியதோர் பித்தத்தின் கல்ல டைப்பு
புரண்டதோர் சிலேட்டுமத்தின் கல்ல டைப்பு
தீன்றியதோர் தொந்தமாங் கல்ல டைப்பு
தேகத்தைப் பற்றியே சிறிது காலம்
தான்றியே சலப்பையில் வந்தி ழிந்து
சருவியே லிங்கத்திற் றரிக்குந் தானே''

யூகி வைத்திய சிந்தாமணி பாடல் 728, பக்கம் 284

The above poem mentioned that Kalladaippu noi is classified into four types. They are:

1. Vali Kalladaippu
2. Azhal Kalladaippu
3. Iyya Kalladaippu
4. Mukkutra Kalladaippu

Vali Kalladaippu:

''தரித்து நாபிக்கு சுருக்கமாய் குற்றிச்
சலமலந்தான் வீழாமற் றம்ப மாகி
வரித்துமே லிங்கத்தில் வலியு மாகி
மருவியதோர் பொத்தியெலாஞ் சுரந்து கட்டி
திரித்தியே கிடைக்கொடாப் பிரட்டலாகித்
தேம்பியே மூச்சுமாய் வயிறு முப்பும்
உரித்ததோர் சதைபோல உவர்ப்பு மாகும்
ஓங்கியதோர் வாதக்கல்ல டைப்பு தானே''

யூகி வைத்திய சிந்தாமணி பாடல் 729, பக்கம் 284

Acute pain felt just below the umbilical region and penis. Scanty micturition obstruction of urine flow. Sometimes mucous discharge in urine, patient unable to sit.

Azhal Kalladaippu

''அடைப்பாகிச் சலந்தானு மருவ லாகி
அயங்காச்சிச் சொருகினாற் போலே காணும்
புடைப்பாகப் பொற்றியெங் கும்பு ழுக்கமாகிப்
பூட்டுப்போல் பிகுவாகிப் பிரட்ட லாகும்
மடைப்பாகி உதிரநிற மாயக்கல் லாகி
வந்தழிந்து லிங்கத்தில் மாட்டிக கொள்ளும்
குடைப்பாகிக் குற்றலாய்க் கூச்சலாகிக்

குதட்டுமே பித்தக்கல் லடைப்பு தானே''

யூகி வைத்திய சிந்தாமணி பாடல் 730, பக்கம் 285

It is characterized by reduced urine output with characteristic burning sensation (similar to introducing a root hot iron needle into the urethera) Excretion of small blood stained stones. Causing pricking pain & tenderness.

Iyya Kalladaippu

''தானா தொப்புளிலே வில்லு போலச்
சலியாமற் சுரந்துமே சற்றே குற்றும்
ஏனான காலோடு கைகள் சந்து
இடுப்புதான் குடைச்சலா யிசிவு காணும் வேனான
லிங்கத்தின் வெண்மை தன்னில்
விறவிறென் றேகடுப்பாகி வியர்வையாகும் தேனான
வெளுப்புக்கல் சிறுகல் லாகிச்
சிக்கலாய் வந்திறங்குஞ் சேட்பந் தானே''

யூகி வைத்திய சிந்தாமணி பாடல்731 பக்கம் 285

It is characterized by excruciating pain in the umbilical region. Pain in the joints of upper and lower extremities. Profuse sweating and expulsion of smell white coloured stones in the urine**.**

Mukkutra Kalladaippu

''வந்திறங்கும் நீர்த்தாரை யடியிற் றானும்
மாவருத்த முண்டாகி வலியு மாகி
நொந்திறங்கி நீர்தானு மருவி பாயும்
நொயதான சிறுமணல் போல் நொறுங்கி கல்லான்
சந்திரங்கி நீர்வழியில் வந்து வீழும்
தாக்கான சிறங்கைக்கல் தினமொன் றுக்கு
துந்திறங்கித் தினந்தினமு மிழந்து கொல்லும்
தொந்தமாங்க லடைப்புச் சூட்டிட் டாயே

யூகி வைத்திய சிந்தாமணி பாடல் 732, பக்கம் 286

Severe pain felt below the uretheral region, Irregular urine output. It is characterized by disintegration of stones into small like granules excreted in the urine and semen.

B) In "Noi Vilakkam"

வளிமுதல் மூன்றினுந் தோன்ற லாலும்
கருநீர் தன்னிற் தோன்ற லாலும்
கல்லடை நால்வகைப் படுமென மொழிப

According to Noi Vilakkam, Kalladaippu Noi is classified into 4 types.

1. Vali Kalladaippu
2. Azhal Kalladaippu
3. Iyya Kalladaippu
4. Karuneer Kalladaippu

வளிக்கல்லடைப்பு குறிகுணங்கள்:

படர்மிகப் படுத்தல் பற்கள் கடித்தல்
நடுங்கல் உந்தியும் குறியும் பிசைதல்
கசடுகீழ் சளியொடு கழலல் அழுதல்
சிறுநீர் துளித்தல் என்பவும் பிறவும்
வளியின் கல்லடைக் குறியென மொழிய
கறுத்துஞ் சிவந்தும் முனைகள் பரந்தும்
வளியின் கல்லது வடிவுனு மென்ப -நோய் விளக்கம்

- Tongue biting, palpitation and chills.
- Lower abdominal colic and pain in the external genitalia.
- Dribbling of Urine, The Stones are blackish red in colour.

அழல்கல்லடைப்பு குறிகுணங்கள்:

"சுட்டென நீரியம் மிகவெப் பிடுத்தலும்
நோதலும் அனலக் கல்லடைக் குறியே
சிவந்தும் கறுத்து மஞ்ச ளாகியும்
சேங்குரு வடிவில் கல்லது தோன்றும்"
-நோய் விளக்கம்

- Burning micturition, Dysuria
- Passing reddish black or yellow coloured stones

ஐயக்கல்லடைப்பு குறிகுணங்கள்:

"நீரியங் குத்தல் திணித்தல் குளித்தல்
எனுமிவை ஐயக் கல்லடைக்குறியே
வெளுத்தும் தேனிற மாகியு மொளிர்ந்தும்
பெருவடி வுடைத்தாம் ஐயக் கல்லடை"
-நோய் விளக்கம்

- Pricking pain with severe intensity while passing urine.
- Fever with rigors
- White or honey coloured shining or luminant large size stone expelled.

கருநீர்க்கல்லடைப்பு குறிகுணங்கள்:

"நீரியம் நோதல் சிறுநீர் தடைப்படல்
விரைவில் கிடுதல் எனுமிவை பிறவும்
கருநீர்க் கல்லடைக் குறியெனமொழிப"

-நோய் விளக்கம்

- Sudden or gradual obstruction to flow of urine
- Excessive Vali kutram breaks the stones into small and large size crystals and expels along with urine, Sudden stoppage of urine stream
- Retention of urine, abdominal pain, Loss of taste, excessive thirst.

C) In "Dhanvanthiri Vaithyam – Part II"

1. Kallarippan
2. Pitha ashmari
3. Silethuma ashmari
4. Sukkila ashmari

Kallarippan:

"சுத்துநீர் நாளந்தன்னீற் சுக்கிலந்தன்னீற் சிலேற்பனம்
பித்தமீ துலர்த்தல் கல்லாய் பீசகிநீ டைத்துக் கொள்ளுங்
கொத்துநீ ரிற்றுவீழுங் கொப்புள்நோ குடம்பு காயுஞ்
சித்தா யருசி யுண்டாஞ் சேர்ந்தகல் லெரிப்பானாமே"

தன்வந்திரி வைத்தியம்

It is learnt from this poem that when kabam and pitham increase, urine and semen dry up, resulting in the formation of stone which in turn lead to obstruction of urinary tract, dysuria, pricking pain in umbilicus, fever and anorexia.

D) In "siddhar Aruvai Maruthuvam"

Kalladaippu noi is classified into four types.

1. Vali kalladaippu
2. Azhal kalladaippu
3. Iyya kalladaippu
4. Veneer or Manal kalladaippu

E) In "Roga Nirnaya Saaram under Roga Nithanam"

Ashmari rogam is classified into five types:

1. Vatha kalladaippu
2. Pitha kalladaippu
3. Kapha kalladaippu
4. Sukkila kalladaippu
5. Swargara Ashmari or Kalladaippu rogam.

F) In "Anubhava vaidhiya Devaragasiyam – I Part"

1. Vatha ashmari
2. Pitha ashmari
3. Kapha ashmari
4. Sukkila ashmari
5. Swargara ashmari or kalladaippu rogam

Anubhava Vaidhiya Devaragasiyam Page-131

3.3.6 SOME DISEASES ASSOCIATED WITH KALLADAIPPU NOI IN SIDDHA TEXT:

உக்கார சூலை (UKKARA SOOLAI)

"குத்து முத்காரசூலை யின்கு ணந்தான்
கோர்வையாய் விலாவுதனில் முதுகில் நெஞ்சில்
அத்தி யினில் நாபியில பானமாங்கு தத்தில்
அதிக துன்மாங்கிசந்தான் வளர்ந்து மேவிப்
பத்துமணற் படுக்கைபோற் சலத்து வாரப்
பதிநெருக்கி மூத்திரமாங் கிரிச்சி யுண்டாய்த்
தத்துசடங் கடுப்பெடுத்து மதிக லங்கித்
தளர்ச்சி யொடுமயக்கமாய்த் தள்ளுந் தானே"

- யூகி வைத்திய சிந்தாமணி – 800 பாடல் 233, பக்கம் 88

Excessive growth of muscles in chest region, back of trunk, umbilicus, anal and urethral orifice followed by stricture of uretheral orifice by sand like crystals blocked in urethera causes dysuria, tiredness, body pain occurs.

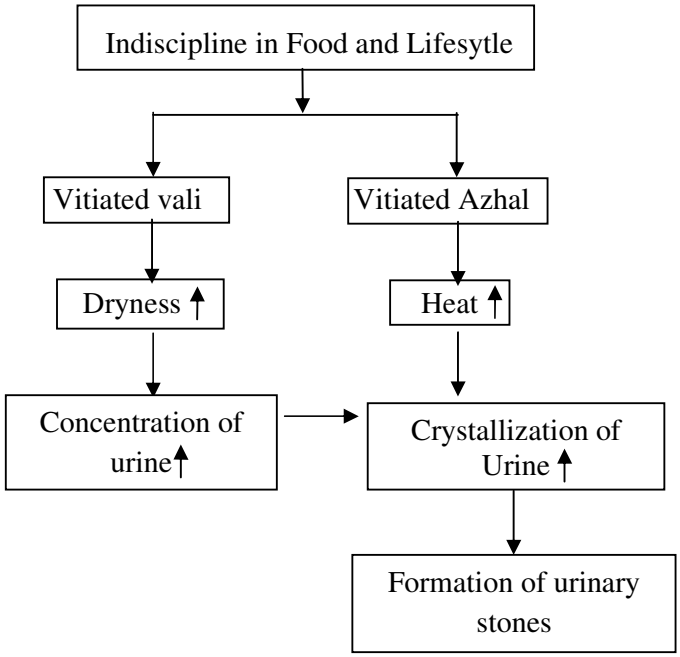
3.3.7 முக்குற்ற வேறுபாடுகள் : (PATHOLOGY)

"வாயுவினால் மலம் சலங்கட்டிடும்
பிரித்திடும் பித்தம் பேரஞ் சலத்தினாலே"

சித்த மருத்துவாங்க சுருக்கம் பக்கம் - 154

Alteration in diet and lifestyle causes the vitiation of the vatha humour for sufficiently enough time, which can further cause the imbalance in either of the other two humours and hence pitham is also deranged resulting in urolithiasis. Vali is responsible for dryners and Azhal is responsible for the heat. This causes decrease in body fluids and increase in concentration of urine and thereby the crystal grows and aggregation takes place in the urinary passage. As (kezhnokkukal) "Abanan" one of the component of ten vayu, is strongly responsible to expel the deposits that will be automatically washed out in urine. If Abanan is not strong enough, the deposited material will not be expelled and pave way for renal stones.

SIDDHA PATHOLOGY & SCIENTIFIC ASPECTS OF KALLADAIPPU



More over Vatham is responsible for maintenance of 14 reflexes including micturition. Therefore body pain, pricking pain in external genitalia and constipation seen in urolithiasis (Kalladaippu) due to altered vatham humour.

Pitham has direct link with urine (i.e) "Pitham Siruneeril Adangum". Therefore symptoms of darked yellow urine, sometimes reddened urine seen in Kalladaippu due to elevated pitham humour.Decreased Kapham humour prones the body constitution to dryness and heat. All these derangements create the alterations in biochemical parameters of Kidney function form the symptoms of urolithiasis

3.3.8 PRINCIPLES OF SIDDHA DIAGNOSIS IN UROLITHIASIS:

Siddhars investigate the cause of the disease the signs and symptoms, complications if any and anatomical (udal kooru) changes to arrive at a diagnosis of a disease. They examine both the body and the disease together to arrive a conclusion regarding the condition or diseases.They followed two paths called “Noi naadal” in simple terms defined as the approach to the disease and “Noi Mudhal Naadal” which is determination of aetiologyof the disease. These diagnostic tools designed by siddhars that they can also determine the risk factor and help in early prediction of the illness. The following are the diagnostic methodologies of urolithiasis in Siddha.

S.No.	Thathuvams	Affected basic principle	Symptoms of Kalladaippu
1.	Uyir thathukkal (3)	1. Vatham (10) Abanan Udhanan	Scanty mituriation, Haematuria, Dysuria, Nausea and vomiting
		2. Pitham (5) Saathagapitham	Dysuria, oliguria
		3. Kabham (5) Santhigam	Pain present in the joints
2.	Udal thathukkal (7)	1. Moolai (bone marrow) increased	Oliguria
		2. Sukkilam (semen) increased	Renal calculus
3.	Iymboothangal (5)	1. Vayu (Air)	Obstruction in genitalis
		2. Thaeyu (fire)	Dryness, heat burning sensation
		3. Appu (water)	Reddened urine
4.	Iymporial / Iyampulangal (5)	1.Mei	Koocherithal
5.	Kanmenthiriyam / Kanmavidayam (5)	1. Eruvai	Constipation
6.	Aasayam (5)	1. Salavasayam	Oliguria
		2. Sukkilavasayam	Pain and burning sensation in external genitalis

7.	Yakkai (3) (General characters)	1. Vatham	"Siruneer porumi Kaduthu vizhum"
		2. Pitham	"Neerum uyarnthu sivappagum"
8.	Manikkadai	9 ¼	"Neer kaduthu siruthu irangam". dysuria and stranguria
		6 ¾	Proned to urolithiasis in 3years of time
9.	Thinai (5)	1. Muthuvenil 2. Karkalam	Affected
10.	Kaalam (7)	1. Neithal 2. Mullai	Affected

3.3.9 நோய் கணிப்பு முறை (DIAGNOSIS AND PROGNOSIS)

The Diagnostic methodology in siddha system in unique and it is made purely on the basis of clinical acumen of the physician. In "Piniyari muraimai" the following principles are

1. Poriyaal arithal - Physical examination
2. Pulanaal arithal - Clinical examination
3. Vinaathal - Medical History

1. PORIYAAL ARITHAL : It means understanding by the five organs of perception.

Mei	–	Ooru (somatic sense) to feel all types of sensation
Vai	-	Suvai (taste) for knowing taste.
Kan	-	Oli (vision) for vision
Mookku	-	Natram (smell) for knowing the smell
Sevi	-	Osai (sound) for hearing

2. PULANAAL ARITHAL : It means understanding by sensing the objections.

Kai	-	All Manocurves
Kal	-	Walking
Vai	-	Speaking
Eruvai	-	Defecation
Karuvai	-	Reproduction

3. VINAATHAL (Interrogation)

The first step in diagnosing a disease by knows their personal history of the patient through Interrogation. The physician should interrogate the patients name, age, native place, socio economic states, food habits, personal habits, present complaints, of history of present illness, history of past illness, through this applied eight tools of investigation (i.e) Envagai Thervugal .

3.3.10 எண்வகைத் தேர்வுகள்:

"அகத்துறு நோயை கரத்தாம லகம்போல்
பகுத்தறிவீர் நாடிப் பரிசம் - தொகுத்த நிறம்
கட்டுவகைச் சொல்மொழி கண்ட மல மூத்திரம் நா
எட்டுவகை யாலு மறிவீர்"

-அகத்தியர் வைத்திய சிந்தாமணி வெண்பா 4000

"நாடி பரிசம் நாநிறம் மொழிவிழி
மலம் மூத்திரமிவை மருத்துவராயுதம்" -தேரையர்
"மெய்குறி நிறந்தொனி விழிநாவிருமலம் கைக்குறி" -தேரையர்

According to Agathiyar vaithiya chinthamani venba- 4000 and saint therayar, the Envagai Thervugal (Eight types of diagnostics) include, Naadi(pulse), Naa (tongue), Niram(colour), Mozhi(voice), Vizhi(eyes), Malam(faeces), Neer(urine) and Sparisam (touch & palpation).

In "Gunavagada Naadi" about the Envagai Thervugal as following.

"தரணியுள்ள வியாதி தன்னை யட்டாங்கத்தால்
தானியறிய வேண்டுவது யேதோ வென்னில்
திணியதோர் நாடிகண்கள் சத்தத்தோடு
தேகத்தினது பரிசம் வருணம் நாக்கு
யிரணமல மூத்தரமாவிவைக ளெட்டும்
யிதம்படவேதான் பார்த்து குறிப்புங்கண்டு
பரணருளால் பெரியோர்கள் பாதம் போற்றி
பண்பு தவறாமல் பண்டிதஞ் செய்வீரே"

குணவாகட நாடி பக்கம் - 129

In "Agathiyar vaithya vallathy" to apply the envagai thervugal for diagnosis of the disease.

"தொகுக்கலுற்ற அட்டவித பரீட்சை தன்னை
துலக்கமுறும் பண்டிதரே தெளிவதாகப்
படுக்கரிய நாடியை நீ பிடித்துப்பாரு
பகர்கின்ற வார்த்தையைப் பார் நாவை பாரு
வகுக்கரிய தேகமென தொட்டுப் பாரு
வளமான சரீரத்தின் நிறத்தைப் பாரு
சகிக்கரிய மலத்தைப் பாரு சலத்தைப் பாரு
சார்ந்த விழிதனைப் பார்த்து தெளிவாய் காணே
நீடிய விழியினாலும் நின்ற நாக்குறிப்பினாலும்
வாடிய மேனியினாலும் மலமொடு நீரினாலும்
சூடிய வியாதி தன்னைச் சுகம்பெற அறிந்து சொல்லே"

அகத்தியர் வைத்திய வல்லாதி

1. Naadi (pulse)

Naadi is nothing but the manifestation of the vital energy that sustains the life within our body. It plays an important role in "Envagai Theruvugal" and it has been considered as foremost thing in assessing the prognosis and diagnosis of various diseases. Any variations occur in three humours it is reflected in naadi. These three humours organize, regularize and integrate basic functions of the human body. So, Naadi serves as a good indicator of all aliments.

"விழுகும் சிலநேரம் விடுபட்டு நீரோடும்
ஒழுகிய வாயுவும் ஒதுங்கினால் நோகாது
வழுகிய மந்தத்தால் வாயுவந்தே புகில்
கழுமி முதிர்ந்திடும் கல்லெரிப்பு ஆகுமே"

திருமூலர் கருக்கிடைவைத்தியம் 600

The above line mentioned that the Vatham and Mantham combined together, Kalladaippu noi may occur.

"அறைந்தோம்வாத ரோகியுடல்
அழறக்ண்முகமும் பல்மலமும்
நிறைந்த விழியில் நீர் வடியும்
நீண்ட நாவு கறுத்திடவும்
திறைந்தமுள்ளாய் தானிருக்குஞ்

சிறு நீர் பொருமி கடுத்து வரும்
உறைந்த நீருங்கருகருத்து
முறையாய் ரோகமு முண்டாமே''

-நோய் நாடல் நோய் முதல் நாடல் திரட்டு– முதல் பாகம், பக்கம் - 165

''மேவியவாதஞ் செய்யும்
குணந்தனை விரும்பிக்கேளு
தாவிய வயிறு மந்தஞ்சந்துகால் பொருத்து நோவாம்
சேவிய தாது நாசஞ்
சிறுத்துடன் சிறு நீர்வீழும்
காவியங் கண்ணினாளே
மலமது கருகிக் காணும்''

-இரத்தின சுருக்க நாடி

The above two poems describes that aggravation of Vatham naadi produces symptoms of Kalladaippu noi.

''எண்ணிய வாதமொன்றும் பித்தமிரண் டெழுந்தாகில்புண்ணென
யுடம்பு நோவாம் புகையெழ யெரியும் நெஞ்சு திண்ணமாய்
நாவரண்டு சிறுத்துநீர்க் கடுத்து விழும் அண்ணவார்
உரைந்தவுண்மை யாயுரு தேவன்தானே''

தன்வந்திரி வைத்தியம் - முதல் பாகம், பக்கம் 11

The above line mentioned when Vatham and Pitham combined together which may result in Kalladaippu noi.

2. Sparism (Touch)

In Sparism the temperature of skin (Thatpam-cold or veppam-heat), smoothness, roughness, sweating, dryness, hard patches, chillness, greasy, swelling abnormal growth of organs and tenderness can be felt.

On examination in Kalladaippu patients tenderness over the lower abdomen, renal angle and lumbar region can be felt, sometimes swelling can be felt (may be due to hydronephrosis)

3. Naa (Tongue)

On examination the physician is expected to observe the features of the tongue and its colour, shape, size, coating, moisture, movement, ulcer, fissure, crust. In

Kalladaippu noi, of the patient suffers from constipation, the tongue would seen to be coated. In karuneer kalladaippu noi the patient has loss of taste sensation.

"கருநீர்கல்லின் வளி சினந்தெழுந்து
சுவைகெடல் வெளிறு மறுப்பு நீர்வேட்கை"

-நோய் விளக்கம்

4. Niram (Colour)

The physician is required to observe the colour of the skin, conjunctiva, tongue, nail bed and hair etc… and make a note if any abnormal colour changes.

Vali udal	-	Black colour
Azhal udal	-	Yellow or red colour
Iyya udal	-	White or yellow colour

In Kalladaippu noi body complexion depends upon the body constitution, pallor of the body is observed in Sukkila ashmari.

"சிக்கிநீர் விழா மலங்கே மணல்விழும் வெளுக்குந்தேகம்
மிக்குணஞ் சுக்கிலாசு மரியசாத் தியமென்றோதோ"

தன்வந்திரி வைத்தியம் - 2 பாகம், பக்கம் 10

5. Mozhi (Speech)

By examining, the mozhi (speech) the vaious characters can be noted such as hoarseness, histery voice, slurring speech, va
rious disorders of speech such as dysarthria can be noted. In kalladaippu noi, there is low pitch voice due to agonizing pain of lower abdomen and burning micturition.

6. Vizhi (Eye)

On examine the colour of eye like pallour, reddish or yellowish discolouration and characters like dryness, odema, lacrimation any visual disturbances.

7. Malam (Stools)

It is necessary to examine the nature (consistency) colour, quantity, hard stools (or) loose stools presence of blood and froth and also pain during defecation.

8. Moothiram (Urine)

Urine examination is one of the good diagnostic tools when compared to other Envagai thervugal.

"தரித்து நாபிக்கு சுருக்கமாய் குற்றிச்
சலமலந்தான் வீழாமற் றம்ப மாகி
வரித்துமே லிங்கத்தில் வலியு மாகி

மருவியதோர் பொத்தியெலாஞ் சுரந்து கட்டி
திரித்தியே கிடைக்கொடாப் பிரட்டலாகித்
தேம்பியே மூச்சுமாய் வயிறு முப்பும்
உரித்ததோர் சதைபோல உவர்ப்பு மாகும்
ஓங்கியதோர் வாதக்கல்ல டைப்பு தானே''

தன்வந்திரி வைத்தியம் பாடல் 729, பக்கம் 284

In Kalladaippu Noi, urine was in high concentrate and sometimes it contains blood stains (Haematuria). Patient having loin to groin pain and burning pain with glans penis while passing urine or end of the urine. Sometimes patients having severe abdominal pain, urine is bitter taste or aromatic odour in nature.

நீர்க்குறிப்பு சிறப்பு:

''தர்க்கசாத்தி திரிக ளானோர்
தங்களிற் றேர்ந்து நாடி
வர்க்கமாம் நாடி தன்னில்
வருவது மயக்கம் மென்றே
உற்றநீர்ப் பரீஷை பாய்ந்தே
யுரைத்தன ரிதற்கு நேராய்
மற்றொரு விதிநூ லில்லை
மருத்துவ கலைவல்லோர்க்கே''

சித்த மருத்துவாங்கச் சுருக்கம், பக்கம் 568

In order to sheet off the ambiguity in the diagnosis of disease through pulse perception. The exponent have charted out a method called Neerikuri – an in camparable method of diagnosis.

சிறுநீரின் பொதுகுணம் :

''வந்தநீருக் கரியெடை மணம் நுரை எஞ்சலேன்
றைந்திய லுளுவை யறைகுது முறையே''

சித்த மருத்துவாங்கச் சுருக்கம், பக்கம் 510

The above line mentioned that the five parameters should be examined in each urine sample.

1. Niram (Colour)
2. Edai (Specific gravity)
3. Nurai (Froth)
4. Naatram (Smell)
5. Enjal (Deposits)

a) Niram (colour)

Nira thogai:

"பீதம் செம்மைபைங் கருமை வெண்மையென்
றோதங் கொழுமையை யொத்துகு நீரே
சித்த மருத்துவாங்கச் சுருக்கம் பக்கம் 510

The above poem reveals that urine colour as follows.

1. Yellow 2. Red, 3. Green 4. Black, 5. White.

கல்லடைப்பு நீரின்குணம் (Colour indicating urinary stone) :

"தீப்புலால் கழுநீர்ச் செயலெனிற் குண்டிக்
காய்த்துர்ப் பலத்தால் கதித்த நீராமத்
துர்ப்பலக் கபமும் சோரியும் கொதிப்புறப்
பற்பக லாகப் பையைப் பதிந்தே"
சித்த மருத்துவாங்கச் சுருக்கம், பக்கம் 520

The colour of the urine look like decomposed flesh cleaned water indicates the presence of kidney stones.

b) Edai (specific gravity)

"மிகத்தடிப் புமமிகத் தேறலும் இன்றெனில்
சுகத்தைத் தரும்மெய்ச் சுபாவநீர் நன்றே"
சித்த மருத்துவாங்கச் சுருக்கம், பக்கம் 528

Urine which is not thick it is considered to be healthy one.

c) Nurai (Froth)

"பந்தமெய்ப் பசையிள கப்படும் பருவத்
தந்தர்ப் பூதமாய நிலமுத் திரத்தில்
சம்பந்தப் படும் ததி நுரைப் புனலே"
சித்த மருத்துவாங்கச் சுருக்கம், பக்கம் 528

In normal condition, urine is frothy in nature. When these is reduced froth in the urine it indicates derangement of vali, Azhal, Iyyam.

d) Naatram (smell)

"காணிதில் சீழும் கலந்திழி மணமுறின்
கருப்பநா பிகளுளுங் காமநாளத்துளும்
விரணமுன் டின்றேன் எய்துமஸ் மரியல
திருத்தலே திண்ண மெனமனத் துன்னே"
சித்த மருத்துவாங்கச் சுருக்கம், பக்கம் 519

The above poem states that foul colour with pyuria is observed in patient with urolithiasis is associated with secondary Urinary tract infection.

e) Enjal (Deposits)

"நார்த்தி நீர்பால் போல
நவையுற்றங் கிழியு மானால்
மாரற்ப முற்ற நீரி
லடிமண்டிக் கிடந்த தானால்
பாரிந்த மெழுகு மாங்காய்
பற்றிய கல்லினாலே
சீருற்ற செய்கை யென்று
தெரிவுறசெப்ப லாமே

சித்த மருத்துவாங்கச் சுருக்கம், பக்கம் 575

The colour of the urine excreted looks like curd water or milk and the presence of white colour and sand like deposits in urine indicated stones in the kidney.

3.3.11நெய்குறி (GENERAL EXAMINATION)

"அருந்துமா றிரதமும் அவிரோ தமதாய்
அ.ர்கல் அலர்தல் அகாலவூண் தவிர்ந்தழற்
குற்றள வருந்தி உறங்கி வைகறை
ஆடிக் கலசத் தாவியெ காதுபெய்
தொருமுகூர்த் தக்கலைக் குட்படு நீரின்
நிறக்குறி நெய்குறி நிருமித்தல் கடனே"

சித்த மருத்துவாங்கச் சுருக்கம், பக்கம் 509

Preparation of the patient:

On the day before the urine examination for Neikuri, the patient should be advised to take balanced diet and quantity of food must be proportionate to his appetite. In addition he/she should have a good sleep.

Method:

After waking up in the early morning, urine should be collected in a glass container and must be examined with in 1 ½ hours. Then a drop of gingely oil should be added through the side of the container without any disturbance. The nature of neikuri should be noted under direct sunlight.

Observation :

Vatha Neer:

"அரவென நீண்டின் அ.ஃதே வாதம்"

சித்த மருத்துவாங்கச் சுருக்கம், பக்கம் 532

In the drop of oil, lengthening like a snake it indicates vathaneer.

Pitha Neer:

"ஆழிபோற் பரவின் அ.ஃதேபித்தம்"

சித்த மருத்துவாங்கச் சுருக்கம், பக்கம் 533

In the drop of oil spreading like a ring, it indicates pitha neer.

KabhaNeer:

"முத்தொத்து நிற்கின் மொழி வதன் கபமே"

சித்த மருத்துவாங்கச் சுருக்கம், பக்கம் 534

In the drop of oil, remaining as that of pearl, it indicates kapha neer.

Thontha neer:

"அரவிலாலியும் ஆழியில் அரவும்
அரவின்முத்தும் ஆழியில் முத்தும்
தோற்றில் தொந்த தோடங்களாமே"

The thontha neer appears as a combination of the above pattern.

Mukkutra neer:

The drop of oil immersing in to the urine, indicates Mukkutraneer.

சாத்தியம், அசாத்தியம் (PROGNOSIS)

"சூட்டிட்ட சாத்தியத்தை சொல்லக் கேளாய்
சுளுக்காகும் வாத்தின் கல்லடைப்பு
பூட்டிட்ட பித்தத்தின் கல்ல டைப்புப்
புகழான சேட்டுமத்தின் கல்ல டைப்பு
மூட்டிட்ட இதுமூன்று மசாத்ய மாகி
முனையான மருந்துகளிற் செம்மை யாகும்
தோட்டிட்ட தொந்தமாங் கல்ல டைப்புத்
தொடுசுறவே கொல்லுமிது சூட்சந் தானே"

யூகி வைத்திய சிந்தாமணி 800

According to *YUGI VAIDHIYA CHINTHAMANI*-800 Vatha, Pitha, Kabha kalladaippu are curable and preventable, but Mukkutra Kalladaippu is not curable.

According to ROGA NIRNAYA SAARAM under Rogam Nithanam, symptoms of kallaidaippu noi like scrotal swelling and anuria are not curable.

3.3.12 LINE OF TREATMENT ADVOCATED AS PER THE SIDDHA PRINCIPLES:

In Urolithiasis, vatham and pitham are the two predominant factors which is responsible for the predisposition of stone formation, it is associated with heat and dryness. So the treatment should be planned towards the settlement of the affected humours as primary goal and secondary objective with medication towards the target action at specific sites and tertiary target to strengthen the system for the prevention of the disease.

As the above mentioned poem, purgation should be given to all patients as per their by condition. Kazhichal marunthu (purgatives) : Decoctions and mediated ghee with coolant properties are used to promote purgative to cleanse the colon bring about a balance of the impaired “TRIDHOSHAM”.

3.3.13 DIET:

Diet plays an important role in both prevention and protection of the body from stone diseases. Diet can contribute to the actiology, management or prevention of recurrence of kidney stone, because dietary ingredients and fluid intake influence the volume, PH and solute concentration of urine.

In urolithiasis, the diet should on with the target to promote the urination, washout the urinary bladder and to expel the small stones.

உணவு பழக்கவழக்கங்கள்:

உண்ணக்கூடியவை:

- குருவை, மணக்கத்தை அரிசி யாலாக்கிய சோறு உண்ண வேண்டும்.
- பார்லி அரிசிக்கஞ்சி, இளநீர் அருந்தவும்.
- முள்ளங்கி, வாழைத்தண்டு, அவரைக்காய், பூசணிக்காய், சுரைக்காய்,கேரட், வெண்டைக்காய் சேர்க்க வேண்டும்.
- தர்பூசணி, பப்பாளி, கொய்யா, எலுமிச்சை சேர்க்கலாம்.
- பசலைக்கீரை, காசினிக்கீரை, கீரைத்தண்டு, வெள்ளரி விதை உண்ணவும்.

தவிர்க்க வேண்டியவை:

- தக்காளி, முட்டைகோஸ், காலிப்ளவர், உருளைகிழங்கு, காளான்.
- பால், காபி, டீ, மதுபானம், பதப்படுத்தப்பட்ட பானங்கள் அருந்தக்கூடாது.
- முட்டை, ஐஸ்கிரீம், சாக்லேட் தவிர்க்கவும்.

Advice :

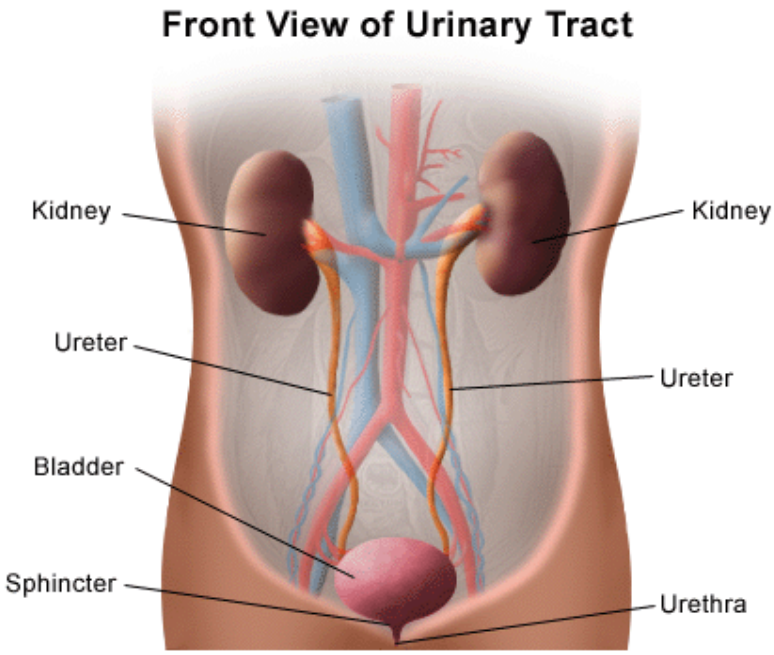
1. Patient should drink large quantity of water (4 litre/day)
2. Patient should reduce salt intake
3. Regarding prevention "Anubhava Vaidhya Deva ragasiyam" states the one should not suppress the excretion of moothiram (Urine) and sukkilam (Seminal fluid) is most predisposing cause for Kalladaippu noi.

3.4 MODERN ASPECT

3.4.1 URINARY SYSTEM

The urinary system also known as the renal system. The urinary system's function is to filter blood and create urine as a waste by-product. The organs of the urinary system include the kidneys, renal pelvis, ureters, bladder and urethra. The kidney and urinary systems help the body to eliminate liquid waste, and to keep chemicals, such as potassium and sodium, and water in balance and regulate blood PH. Following filtration of blood and further processing, wastes (in the form of urine) exit the kidney via the ureters, tubes made of smooth muscle fibres that propel urine towards the urinary bladder, where it is stored and subsequently expelled from the body by urination (voiding) through urethera.

FIG.1.FRONT VIEW OF URINARY TRACT

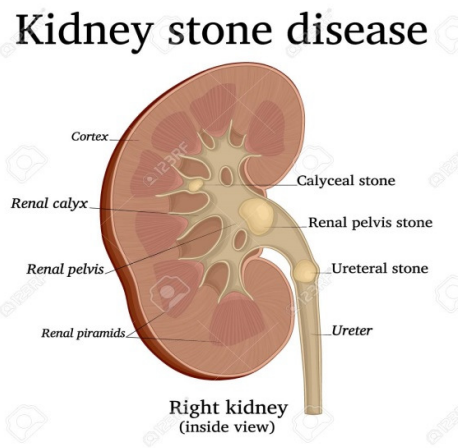


3.4.2. UROLITHIASIS

Urolithiasis is the formation of stones (calculi) anywhere in the urinary tract in the renal pyelocalyceal system, ureter, bladder, and urethra). It is the third most common urinary tract disease in humans. According to localization, there is renal lithiasis (nephrolithiasis), ureter lithiasis (stones in the tubules through which urine flows from kidneys to the bladder), bladder lithiasis and urethral lithiasis (stones in the tubule ejecting urine from the bladder outwards). The development of the stone is related to decreased urine volume or increased excretion of stone –forming

components such as calcium, oxalate, urate, cystine, xanthine, and phosphate. It is estimated that approximately 2% of the population experiences renal stone disease at some time in their life with male-female ratio of 2:1. The peak incidence is observes in 2nd and 3rd decades of life.

FIG.2.KIDNEY STONE DISEASE



3.4.3 EPIDEMOLOGY:

Hereditary:

For patients with kidney stones caused by any one of the following rare conditions:

- Hypercalciuria
- Cystinuria
- Hypocitraturia
- Enteric hyperoxaluria (EH)
- APRT deficiency
- Primary hyperoxaluria (PH)

Age:

The peak incidence of kidney stone in the age of 20-60 years.

Sex:

Mostly kidney stone affected men than women.

Geographical influence:

The prevalence of urinary calculi is higher in those who live in high attitude, high temperature, and tropical areas.

Climate and seasonal factors:

Incidence of urinary calculi and aggravation of symptoms are noted during summer months.

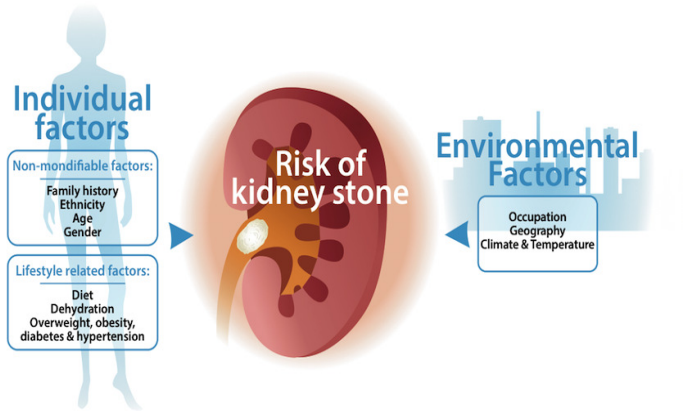
Nutrition:

- ❖ Lack of liquid foods
- ❖ Excessive sodium intake
- ❖ Increased meat from beef, pork, poultry, fish and seafood
- ❖ Citrate fruits and vegetables
- ❖ White sugar

Dehydration:

Not drinking enough water each day may increase risk of kidney stones people who live in warm climates and those who sweat a lot may be at higher risk than others.

FIG.3.PREDISPOSING FACTORS FOR URINARY STONES:



RISK FACTOR RELATED TO OTHER DISEASE:

- o Parathyroid disorders
- o Gout
- o Urinary
- o tract infection
- o Bed ridden patients
- o Previous catherization

FACTORS RELATED TO TAKING DRUGS:

- ➢ Antacids
- ➢ Vitamin C
- ➢ Aspirin

3.4.4 AETIOLOGY

1. CALCIUM STONES:

Aetiology of calcium stones is variable.

1.Hyperparathyroidism

2.Inflammatory bowel disease

3.Dent disease

4.Gastric bypass surgery

5.Diabetes mellitus

6.Over weight.

2. ***MIXED (STRUVITE) STONES:***

Struvite stones account for 15% of renal calculi.Usual organisms include.

- Proteus
- Pseudomonas
- Klebsiella species

3. URIC ACID STONES:

Uric acid stones are frequently formed in cases with hyperuricaemia and hyperuricosuria such as due to primary gout or secondary gout due to myeloproliferative disorders (e.g. in leukaemias), especially those on chemotherapy, and administration of uricosuric drugs (e.g. salicylates, probenacid). Other factors contributing to their formation are acidic urine pH (below 6) and low urinary volume.

3. CYSTINE STONES:

Cystine stones are associated with cystinuria due to natural substance called 'cystine' leak into urine.

4. ***OTHER CALCULI:***

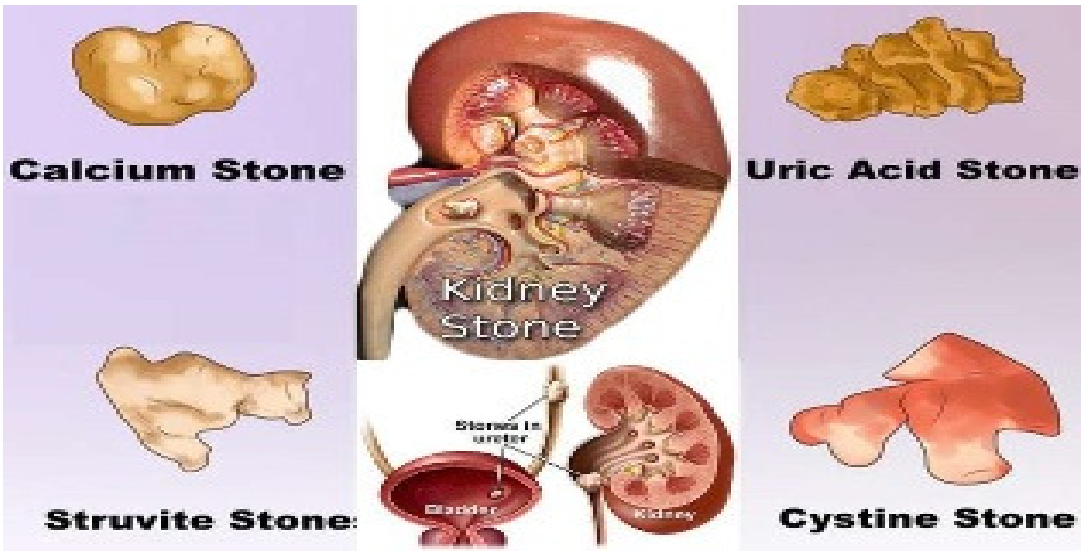
Are caused due to inherited abnormality of enzyme metabolism.

3.4.5 TYPES OF URINARY STONES:

There are four types of urinary calculi, they are

1. Calcium type of stone-75%
2. Mixed (struvite) type of stone-15%
3. Uric acid type of stone-6%
4. Cystine type of stone-2%
5. other types-<2%

Figure.3.4.5.TYPES OF URINARY STONES



1. CALCIUM STONES:

Most kidney stones are made up of calcium compounds, especially calcium oxalate. Calcium stones are the most common comprising about 75% of all renal calculi.the different type of calcium stones are calcium oxalate and calcium phosphate.

2. MIXED (STRUVITE) STONES:

About 15% of urinary calculi are made of magnesium-ammonium-calcium phosphate, often called ***struvite*;** hence mixed stones are also called as struvite stones' or' triple phosphate stones. Struvite stones are yellow-white or grey. They tend to be soft and friable and irregular in shape. ***'Staghorn stone'*** which is large, solitary stone that takes the shape of the renal pelvis where it is often formed is an example of struvite stone. They can also be called infection stones if they occur with kidney or urinary tract infections. These types of kidney stones sometimes are also called staghorn calculi if they grow large enough.

3.URIC ACID STONES:

Uric acid stones are one of four major type of kidney stone. Uric acid stones are smoothing, yellowish-brown, hard and often multiple. On cut section, they show laminated structure.Uric acid stones form when the levels of uric acid are too high.

4. CYSTINE STONES:

Cystine stones comprise less than 2% of urinary calculi. Cystine stonesare small, rounded, smooth and often multiple. They are yellowish and waxy. They occur in both men and women who have the genetic disorder cystinuria.

5. OTHER CALCULI:

Less than 2% of urinary calculi consist of other rare types such as Xanthine stones.

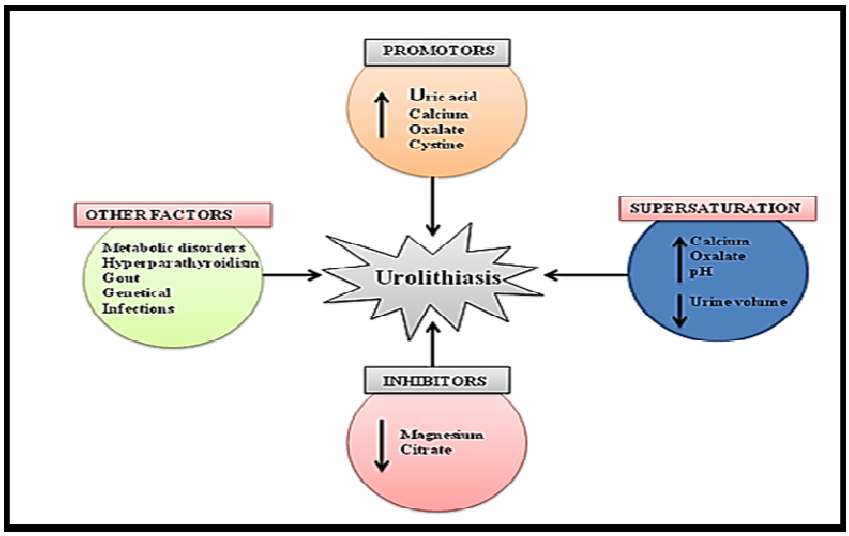
Drug induced stone

These constitute the rare forms of stones which are drug induced forms that results from various drugs like indanavir, triamterine, flouroquinolones, primidone, tetracyclines, magnesium trisilicate and sulfonamides. In addition to this, other drugs like calcitriol, corticosteroids, furosemide and acidifiers can predispose the individual to hypercalciuria induced calcium uroliths.

In other cases like ascorbic acid and allopurinol therapy, there exist implications of hyperoxaluria and hyperxanthuria induced lithogenesis . Topiramate, a new anti epileptic drug also implicate the calcium uroliths by its renal tubular acidosis induced by its carbonic anhydrase enzyme. HIV-positive patients are more prone to develop these drugs induced stones when they are treated with lithogenic drugs like indinavir and sulfamides (sulfamethoxazole and sulfadiazine).

3.4.6 PATHOGENESIS OF STONE:

FIG.4.PATHOGENESIS OF KIDNEY STONE



Urinary stones usually arise because of the breakdown of a delicate balance between solubility and precipitation of salts. The kidneys must conserve water, but they must excrete materials that have a low solubility. These two opposing requirements must be balanced during adaptation to diet, climate, and activity. The problem is mitigated to some extent by the fact that urine contains substances that inhibit crystallization. These protective mechanisms are less than perfect. When the urine becomes supersaturated with insoluble materials, because excretion rates are excessive and/or because water conservation is extreme, crystals form and may grow and aggregate to form a stone.

SUPERSATURATION:

CALCIUM KIDNEY STONES:

A solution in equilibrium with crystals of calcium oxalate is said to be saturated with respect to calcium oxalate. In these patients urine organic molecules most weaken links between supersaturation and crystal formation.As a consequence, clinical supersaturation use depends on the principal maxim.

URIC ACID KIDNEY STONES

By contrast supersaturation links so strongly to uric acid kidney stones we need no maxims.Reducing supersaturation below 1 prevents the stones. Nor does anyone doubt that urine pH controls uric acid supersaturation.No one will attempt a formal trail of potassium citrate – which raises urine pH – for uric acid kidney stones.

CYSTINE KIDNEY STONES:

This organic crystal forms when urine is supersaturated with cysteine because transport defects in the kidneys lead to excessive excretion.Though not easy to measure commercially available urine cystine supersaturation gives reliable results, even despite thiol binding drugs.

CRYSTALLIZATION:

When urine supersaturation exceeds the upper limit of metastability, crystals begin to nucleate. Cell debris and other crystals present in the urinary tract can serve as templates for crystal formation, a process known as *heterogeneous nucleation.* Heterogeneous nucleation lowers the level of supersaturation required for crystal formation. Once formed, crystal nuclei will grow in size if urine is supersaturated with respect to that crystal phase. Multiple crystals can then aggregate to form a kidney stone.

In order for a kidney stone to form, crystals must be retained in the renal pelvis long enough to grow and aggregate to a clinically significant size. The mechanism of crystal retention has been a matter of much debate. Recent studies have shown that common calcium oxalate kidney stones form as overgrowths on apatite plaques in the renal papillae. These plaques, called Randall's plaques, provide an excellent surface for heterogeneous nucleation of calcium oxalate salts. The Randall's plaques begin in the deep medulla in the basement membrane of the thin limb of the loop of Henle and then spread through the interstitium to the basement membrane of the papillary urothelium. If the urothelium becomes damaged, the plaque is exposed to the urine, and calcium oxalate crystallization and stone formation begins.

INHIBITORS OF CRYSTAL FORMATION:

Urine contains potent inhibitors of nucleation, growth, and aggregation for calcium salts. Inorganic pyrophosphate is a potent inhibitor that appears to affect formation of calcium phosphate more than calcium oxalate crystals. Citrate inhibits crystal growth and nucleation, although most of the stone inhibitory activity of citrate is due to lowering urine supersaturation via complexation of calcium. Other urine components such as glycoproteins inhibit calcium oxalate crystallization.

1. CALCIUM STONES:

The mechanism of calcium stone formation is explained on the basis of imbalance between the degree of super saturation of the ions forming the stone and the concentration of inhibitors in the urine. Most likely site where the crystals of calcium oxalate and/or calcium phosphate are precipitated is the tubular lining or around some fragment of debris in the tubule acting as nidus of the stone. The stone grows, as more and more crystals are deposited around the nidus. A number of other predisposing factors contributing to formation of calcium stones are alkaline urinary pH, decreased urinary volume and increased excretion of oxalate and uric acid.

2. MIXED (STRUVITE) STONES:

Struvite stones are formed as a result of infection of the urinary tract with urea-splitting organisms that produce urease.

3. URIC ACID STONES:

The solubility of uric acid at pH of 7 is 200 mg/dl while at pH of 5 is 15 mg/dl. Thus, as the urine becomes more acidic, the solubility of uric acid in urine decreases and precipitation of uric acid crystals increases favouring the formation of uric acid stones. Hyperuricosuria is the most important factor in the production of uric acid stones, while hyperuricaemia is found in about half the cases.

4. CYSTINE STONES:

The resultant excessive excretion of cystine which is least soluble of the naturally occurring amino acids leads to formation of crystals and eventually cystine calculi.

3.4.7 CLINICAL SYMPTOMS:

- Sudden renal colic or ureteric colic.
- Radiating pain towards the groin and testicular region.
- Intermittent biliary or intestinal colic.
- Dysuria.
- Oliguria.
- Haematuria
- Urinary retention.
- Rigors and fever.
- Nausea and vomiting.

3.4.8 DIAGNOSIS:

The diagnosis of kidney stones on the basis of, information obtained from history and physical examination.

Other tests:

- Complete blood count (CBC), looking for neutrophilia, (increased neutrophil granulocyte count) suggestive of bacterial infection, as seen in setting of struvite stones.
- Blood tests for calcium, phosphorus, uric acid, and electrolytes.
- Blood urea nitrogen (BUN) and creatinine to assess kidney functioning.
- Urine analysis- microscopic examination of the urine, which show
- Red blood cells.
- Epithelial cells.
- Urinary casts and crystals.
- Pus cells.
- Abdomen x-rays.
- Ultra sound examination of the kidney.
- Intra venous pyelogram.
- Retrograde pyelogram.
- MRI of the abdomen and kidneys.
- Abdomen CT scan.
- Stone analysis is done of collected stones can establish their composition, which in turn can help future preventive and therapeutic management.

3.4.9 DIFFERENTIAL DIAGNOSIS:

- Appendicitis.
- Cholecystitis and cholelithiasis.
- Ectopic pregnancy
- Pelvic inflammatory disease.
- Pancreatitis.
- Gastric and duodenal ulcers.
- Pyelonephritis.
- Diverticulitis.

3.4.10. COMPLICATIONS:

- Abscess.
- Urinary fistula formation.
- Ureteral scarring and stenosis.
- Hydronephrosis.
- Acute or Chronic Renal Failure.

3.4.11 DIET FOR URINARY STONES:

CALCIUM STONES:

- A diet that increases blood and urine levels of calcium, such as caffeine and sodium.
- Coffee, chocolate, cool drinks must be avoided.
- Vitamin B6 is to reduce the urinary calcium levels.
- Oxalate rich foods like spinach, beet, black tea, and nute are also avoided.
- Also avoid vitamin C rich foods, because it converts to oxalate, oxalate excreted in urine.

STRUVITE STONES:

- They modify their diet to increase the acidity of urine to inhibit bacterial growth. Urine acidifiers include specific tablets, animal proteins, and citrus fruits.

URIC ACID STONES:

- Avoid animal sources of protein.
- Even vegetable sources of protein like pulses and grains are also restricted.

CYSTINE STONES:

- Avoid fish and grains containing protein.
- The food which help to raise the PH of the urine such as vegetable juices and fruits can be take

CHAPTER-IV

MATERIALS AND METHODS

4.1 STUDY DESIGNS AND CONDUCT OF THE STUDY:

A Prospective open labelled phase-II non- randomized clinical trial on "KALLADAIPPU" was carried out in the Post Graduate Department Of Pothu Maruthuvam from the study period of AUGUST 2018- JUNE2019 at Government Siddha Medical College and Hospital, Palayamkottai-6270O2. Tirunelveli, Tamilnadu. The study was approved by Institutional Ethics Committee (IEC) (IEC, GSMC/IV-IEC/2017-Br-I-02/29.05.2017)

The study was registered in Clinical Trials Registry-India (CTRI) and the reference number is CTRI/ 2018/03//012710- MARCH 21 The study was approved by Institutional Animal Ethics Committee (IAEC), K.M College of Pharmacy, Madurai held on 01.05.2018. CPCSEA approval number: IAEC /P.BERNATH/ TNMGRMU/ MD(S) /321611002 / KMCP /24/ 2018

4.2 SAMPLE DESIGN:

Totally 40 patients were selected in Kalladaippu Noi, among 40 (20-Outpatients and 20-Inpatients) of both sexes between age groups of 20-60 years, were recruited for study and treated with the trial drug till the end of the study period.

4.3 CRITERIA FOR THE SELECTION OF PATIENTS:

For the present study, patients were selected based on the following criteria

- Ultra sonogram report, indicating the presence of renal calculus.
- Urine analysis report, indicating the presence of crystals, albumin and RBCS deposition in the urine.
- Clinical history of patients with the following symptoms
  Renal colicky pain, Burning micturition, Oliguria, Haematuria, Nausea and Vomiting.

4.4. EXCLUSION CRITERIA

- Age below 20 years and above 60 years
- Chronic Appendicitis
- Cholecystitis
- Pyelonephritis
- Recurrent UTI
- Diabetes mellitus.

- Metabolic disorders like Hyperthyroidism, Hyperparathyroidism
- Pelvic inflammatory disease
- Chronic Renal Failure

4.5. WITHDRAWAL CRITERIA

- Intolerance to the drug and development of adverse reactions during drug trial.
- Poor patient compliance & defaulters.
- Patient turned unwilling to continue in the course of clinical trial.
- Occurrence of any serious illness
- Any other severe acute illness
- Hypersensitivity of drugs to the patients

TERMINATION CRITERIA

- Not reporting subsequently
- Voluntary termination

STANDARD PREPARATORY PROCEDURE OF NVK

SOURCE OF TRIAL MEDICINES

The raw drugs required for the preparation of **NERUNJI VER KUDINEER** are collected by me from my garden and the raw drugs are authenticated by Medicinal botanist of Govt. Siddha Medical College, Palayamkottai. Then, the drugs are purified and medicines are prepared in the Gunapadam Practical hall, Govt. Siddha Medical College, Palayamkottai.

NERUNJI VER KUDINEER

A)INGREDIENTS

Drug	Botanical name&family	Quantity	Important phytochemicals	Action
Nerunji ver	*Tribulus terrestris.L Zygophyllaceae*	5gm	Dioscin Protodioscin Diosgenin	Diuretic Refrigerant Astringent
Sirupeelai ver	*Aerva lanata.L Amaranthaceae*	5gm	Apigetrin Rutin Myricetin	Diuretic Lithotriptic
Sirukeerai ver	*Amaranthus tricolor.L Amaranthaceae*	5gm	Amaranthin Isoamaranthin	Diuretic
Seeragam	*Cuminum cyminum.L Apiaceae*	5gm	Carvacrol Carvone Pinene	Carminative
Water		400 ml		

B) PURIFICATION OF DRUG

Nerunji ver

Cleaned and make it dried in shade

Sirupeelai ver

Cleaned and make it dried in shade

Sirukeerai ver

Cleaned and make it dried in shade

Seeragam

Cleaned and make it dried in shade

C) PROCESS OF PREPARATION

The purified drug 5 gm of Nerunji ver, 5 gm of sirupeelai ver 5 gm of sirukeerai ver and 5 gm of seeragam are dried and powdered, then it is added with 400 ml of water and boiled until it is reduced to one fourth of its level and made kashayam to dispense for patients.

Dosage **:** 100 ml twice a day.

Duration **:** 30 days

Dispensing

For the out-patients, the trial drug was given in 40 gm packets for two days, they are instructed separately for preparing the decoction

For the in-patients, the trial drug dispensed directly by me.

4.6. TREATMENT

NERUNJI VER KUDINEER (INTERNAL MEDICINE)

Reference : AATHMARATCHAMIRTHAM ENNUM VAIDHYA SARASANGIRAGAM, Pg. No. 349, Gandhasamy Mudhaliyar

Dosage : 100 ml BID - Morning and Evening.

Duration : 30 days.

4.7. COLLECTION AND MAINTENANCE OF PATIENT'S DATABASE:

A proforma was prepared to collect details about the patient's personal and family history, present symptoms, history of recent and past illness, laboratory investigations (including urine and blood analysis). Ultra sonogram, method adopted for the purpose of treatment and management of the disease and follow-up procedures. The details collected were recorded in proforma for each individual patient and database was maintained for all the patients.

4.8. SELECTION OF TRIAL MEDICINE:

The trial medicine, NERUNJI VER KUDINEER (Internal) is selected based on their medicinal values in treating KALLADAIPPU NOI, mentioned in the Siddha literature AATHMARATCHAMIRTHAM ENNUM VAIDHYA SARASANGIRAGAM Page.no. 349.

The ingredient was collected, purified properly and prepared according to the literature. The drug is given to the patients for the entire course of treatment. References are enclosed in ANNEXURE-I

4.8.1 Pre Clinical Analysis of Trial Medicine:

All the pre clinical studies of my trial drug had included Bio chemical analysis, acute toxicity studies and Pharmacological studies has done and cross checked before beginning the trial.

A) Biochemical Analysis:

Biochemical analysis of the trial medicine was performed at the Biochemistry unit of Government Siddha Medical College and Hospital, Palayamkottai. Experiments were conducted by the unit by following the standard procedures to known the presence of minerals. The results of the Biochemical Analysis and Inferences are given in results and observation.

B) Phytochemical Analysis:

It was performed at the K.M.COLLEGE OF PHARMACY, MADURAI. Experiments were conducted by the unit by following standard procedures to known the presence of minerals and microbiology. The results of the phytochemical analysis and results are given in results and observation.

C) Pharmacological Analysis:

Pharmacological actions of the trial medicine were studied at K.M College of Pharmacy, Madurai. Experiments were conducted with albino rats by following the standard procedures to determine the Pharmacological actions like Lithotriptic, Analgesic and diuretic effect. The results and inferences are given in results and observation.

D) Toxicity studies:

The toxicity study for my trial drug was done by K.M COLLEGE OF PHARMACY, MADURAI. The results and interferences are given in results and observation.

4.8.2 .Assessment:

A.Clinical assessment:

The patients were subjected to the following investigations to establish the diagnosis. The investigations were carried out regularly before and after the treatment.

- Routine laboratory investigations such as blood examination was tested biochemically to known the present functional status of the body and also urine tests was tested to known any depositions and other pathological constituents.
- All the patients were subjected to USG Abdomen before and after the treatment. The USG reports of few patients are enclosed in ANNEXURE-II.

b.Siddha assessment:

- Poriyaal arithal
- Pulanaal arithal
- Vinaathal
- Mukkuttra nilaigal
- Udal kattukal
- Envagai thervugal
- Nilam, Kaalam, Thegi

4.9. OUTCOME OF THE STUDY:

The outcome of the study was measured by complete reduction of clinical symptoms and clearance /reduction in the size of renal calculus by conform USG-Abdomen, using the following Urolithiasis symptoms score. The score of each case at the time of enrolment and at the end of treatment were compared and on its basis the patient was informed that he/she was symptoms free and cured.

Urolithiasis Symptom Score:

(Circle relevant number on each line)

1. Pain/colic	0- No pain	1- Mild pain	2 -Moderate pain	3- Severe Pain
2. Haematuria	0 –No Haematuria	1- Microscopic	2- Persistent	3 –Gross
3. Dysuria	0 -No dysuria	1- Mild dysuria	2- Moderate dysuria	3- Severe
4. Stone	1- Single stone		2- MultipleStone	
5. Size of Stones	0- Grade < 03mm	1-3 mm to < 4 mm	2-4 mm to < 5 mm	3-5 mm and Above
6. Position of stone in Kidney	0- No stone in Kidney	1-Pelvic ureteric junction	2- Pelvis of kidney	3 Calyces of Kidney
7. Position of stone in ureter	0- No stone in Ureter	1- Lower part of Ureter	2- Middle of ureter	3- Upper part of Ureter
8. Position of stone in Bladder	0 -No stone in Bladder	1 -Base of Bladder	2- Intramural ureter	

Total scoring – 22, 1-7 mild, 8-14 moderate, 15-22 severe.

Symptoms score – (Some of 8 circled numbers)

Statistical analysis:

The collected data's are presented in the form of percentage and figures and analysed using the SPSS 20.0(IBM). Data were expressed as Mean and Standard deviation. The significance of the difference between the mean of the baseline and final examinations was tested using the Paired "t" test. A probability value of <0.05 was considered to be statistically significant.

CHAPTER V

OBSERVATION AND RESULTS

5.1. PRECLINICAL STUDY OF NERUNJI VER KUDINEER:

5.1.1. Biochemical analysis:

Preparation of the extract

5 gm of drug was weighted accurately and placed in a 250ml clean beaker then 50ml of distilled water is added and dissolved well. Then it is boiled well for about 10 minutes. It is cooled and filtered in a 100ml volumetric flask and then it is made up to 100ml with distilled water. This fluid was taken for analysis.

QUALITATIVE ANALYSIS

S. NO	EXPERIMENT	OBSERVATION	INFERENCE
1	**TEST FOR CALCIUM** 2 ml of the above prepared extract is taken in a clean test tube. To this add 2 ml of 4% ammonium oxalate solution	A White precipitate is formed	presence of calcium
2	**TEST FOR SULPHATE** 2 ml of the extract is added to 5% barium chloride solution	A white precipitate is formed	presence of sulphate
3	**TEST FOR CHLORIDE** The extract is added with silver nitrate solution	No white precipitate is formed	Absence of chloride
4	**TEST FOR CARBONATE** The extract is treated with concentrated HCL	No brisk effervescence is formed	Absence of carbonate
5	**TEST FOR STARCH** The extract is added with weak iodine solution	Blue color is formed	Presence of starch
6	**TEST FOR FERRIC IRON** The extract is acidified with glacial acetic acid and add potassium ferrocyanide	No blue colour is formed	Absence of ferric iron

7	**TEST FOR FERROUS IRON** The extract is treated with concentrated nitric acid and ammonium thiocyanate solution	Blood red colour is formed	presence of ferrous iron
8	**TEST FOR PHOSPHATE** The extract is treated with ammonium molybdate and concentrated nitric acid	No yellow precipitate is formed	Absence of phosphate
9	**TEST FOR ALBUMIN** The extract is treated with Esbatch's reagent	No yellow precipitate is formed	Absence of albumin
10	**TEST FOR TANNIC ACID** The extract is treated with ferric chloride	No blue black precipitate is formed	Absence of tannic acid
11	**TEST FOR UNSATURATION** Potassium permanganate solution is added to the extract	It gets decolourised	presence of unsaturated compounds
12	**TEST FOR REDUCING SUGAR** 5 ml of benedict's qualitative solution is taken in a test tube and allowed to boil for 2 minutes and add 8- 10 drops of the extract and again boil it for 2 minutes	No colour change occurs	Absence of reducing sugar
13	**TEST FOR AMINO ACID** One or two drops of the extract is placed on a filter paper and dried well. After drying 1% Ninhydrin is sprayed over the same and dried well	No violet colour is formed	Absence of Amino acid
14	**TEST FOR ZINC** The extract is treated with potassium ferrocyanide	No white precipitate is formed	Absence of zinc

From above table no 5.1.1 Analysis was noted that the ***presence of caicium, sulphate, starch, ferrous ion and unsaturated compounds.***

5.1.2.Phytochemical analysis:

Table:5.1.2.Qualitative phytochemical analysis of NERUNJI VER KUDINEER

	OBSERVATION	**INFERENCE**
1.Alkaloids	An orange red precipitate produced	Presence of alkaloids
2.Flavanoids	No characteristic change	Absence of flavonoids
3.Phenols	A blue or green colour was formed	Presence of phenols
4.Glycosides	Yellow colour was formed	Presence of glycosides
5.Steroids	A red colour was produced in the chloroform layer	Presence of steroids
6.Tannins	No characteristic change	Absence of tannins
7.Saponins	No characteristic changes	Absence of saponins
8.Terpenoids	Red colour layer was formed	Presence of terpenoids

The above table no.5.1.2 The Qualitative Phytochemical analysis was resulted in the ***presence of Alkaloids, Phenols, Glycosides, Steroids, Tannins and Terpenoides.***

5.1.3. Anti –microbial analysis of Nerunji ver Kudineer

Sample Code	**Bacteria Strains Name**				
	Staphylococcus aureus (G+)	***Streptococcus mutans (G+)***	***Bacillus***	***Klebsilla pneumonia (G-)***	***E – coli (G-)***
NVK	15	14	11	-	10
PC	27	15	27	27	25
NC	-	-	-	-	-

Keys ***PC*** **-** ***Positive Control (Streptomycin)***

NC **-** ***Negative Control***

- **-** ***No Zone***

Mm **-** ***Millimetre***

G+ **-** ***Gram Positive Organis***

G- **-** ***Gram Negative Organism***

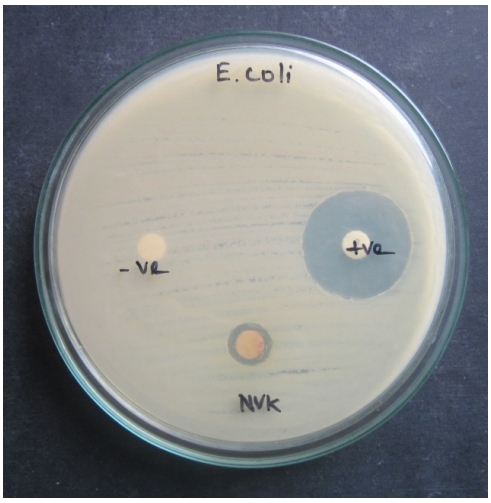
Fig.1.Staphylococcus aureus

Fig.2.Streptococcus mutans

Fig.3.Bacillus subtilis

Fig.4.Klebsiella pneumoniae

Fig.5.E.coli



The above table no 5.1.3 showed NERUNJI VER KUDINEER was sensitive to Staphylococcus aureus, Streptococcus mutans,Bacillus subtilis and E.coli. Not sensitised to Klebsiella pneumonia.

5.1.4. PHARMACOLOGICAL STUDIES:

5.1.4.1. LITHOTRIPTIC ACTIVITY OF NVK

Table:1 Effect on Urinary output in Urolithiasis induced rats

Days	GP1	GP2	GP3	GP4	GP5
0	6.25±0.42	6.30±0.46	6.45±0.70	6.75±0.72	7.45±0.65
14	6.80±0.68	5.90±0.42**a	7.50±0.88**b	8.20±1.35**b	10.42±1.64**b
28	7.45±0.85	5.40±0.26**a	7.65±1.32**b	9.20±1.62**b	10.80±1.80**b

Table:2 & 3 EFFECT ON URINARY BIOCHEMICAL PARAMETERS ON 14^{TH} DAY & 28^{TH} DAY

GP	Protein (mg/dl)	Magnesium (mg/dl)	Calcium (mg/dl)	Uric acid (mg/dl)	Creatinine (mg/dl)	Oxalate (mg/dl)	Phosphate (mg/dl)
GP_1	74.90± 1.70	3.92± 0.48	5.48± 0.74	8.80± 0.75	0.82± 0.16	18.75± 1.52	37.65± 2.82
GP_2	152.28± 4.45**(a)	1.34 ± 0.24**(a)	27.22± 1.87**(a)	17.58 ± 1.45**(a)	1.56 ± 0.22**(a)	31.70 ± 3.32**(a)	78.63 ± 4.36**(a)
GP_3	88.35 ± 3.90 **(b)	2.62 ± 0.30**(b)	19.30 ± 2.22**(b)	11.68 ± 0.88**(b)	0.98 ± 0.17**(b)	25.25 ± 2.65**(b)	46.60 ± 3.82**(b)
GP_4	86.45 ± 3.72**(b)	2.35 ± 0.48**(b)	12.36 ± 0.76**(b)	11.25 ± 0.56**(b)	0.94 ± 0.16**(b)	23.75 ± 2.48**(b)	42.35 ± 3.24**(b)
GP_5	80.35± 2.75**(b)	3.28 ± 0.60**(b)	16.55 ± 0.38**(b)	7.65 ± 0.75**(b)	0.82 ± 0.17**(b)	21.30 ± 1.70**(b)	36.25 ± 2.48**(b)

Table.4 EFFECT ON SERUM PARAMETERS ON 28TH DAY

GP	Protein (mg/dl)	Magnesium (mg/dl)	Calcium (mg/dl)	Uric acid (mg/dl)	Creatinine (mg/dl)	Oxalate (mg/dl)	Phosphate (mg/dl)
GP_1	76.87 ±3.82	4.40 ±0.45	7.28 ±0.63	3.47 ±0.73	0.95 ±0.32	18.60 ±1.43	33.22 ±3.45
GP_2	165.28 ±7.25$^{**(a)}$	1.82 ±0.60$^{**(a)}$	22.75 ±1.62$^{**(a)}$	12.45 ±1.32$^{**(a)}$	1.68 ±0.60$^{**(a)}$	51.38 ±4.44$^{**(a)}$	81.48 ±4.82$^{**(a)}$
GP_3	91.28 ±5.64$^{**(b)}$	2.50 ±0.43$^{**(b)}$	13.65 ±1.12$^{**(b)}$	8.58 ±0.47$^{**(b)}$	1.28 ±0.76$^{**(b)}$	26.81 ±2.61$^{**(b)}$	45.73 ±3.42$^{**(b)}$
GP_4	88.74 ±5.65$^{**(b)}$	3.94 ±0.58$^{**(b)}$	11.65 ±0.94$^{**(b)}$	8.25 ±0.42$^{**(b)}$	1.27 ±0.46$^{**(b)}$	24.33 ±2.47$^{**(b)}$	44.46 ±3.23$^{**(b)}$
GP_5	84.70 ±4.88$^{**(b)}$	3.55 ±0.46$^{*(b)}$	11.28 ±0.48$^{**(b)}$	7.30± 0.34$^{**(b)}$	1.24 ±0.40$^{**(b)}$	21.32 ±2.18$^{**(b)}$	41.65 ±2.30$^{**(b)}$

GP	Magnesium (mg/dl)	Calcium (mg/dl5)	Uric acid (mg/dl)	Creatinine (mg/dl)	Oxalate (mg/dl)	Phosphate (mg/dl)
GP_1	4.92 ±0.54	10.65 ±1.54	3.36 ±0.26	0.52 ±0.29	6.42 ±0.72	13.82 ±1.42
GP_2	1.64 ±0.42$^{**(a)}$	17.52 ±2.45$^{**(a)}$	9.74 ±1.32$^{**(a)}$	1.24 ±0.59$^{**(a)}$	13.58 ±1.72$^{**(a)}$	29.28 ±3.55$^{**(a)}$
GP_3	3.78 ±0.55$^{**(b)}$	11.82 ±1.64$^{**(b)}$	4.28 ±0.82$^{**(b)}$	0.82 ±0.54$^{**(b)}$	9.56 ±0.96$^{**(b)}$	24.26 ±2.78$^{**(b)}$
GP_4	3.89 ±0.27$^{**(b)}$	11.76 ±1.52$^{*(b)}$	4.22 ±0.44$^{**(b)}$	0.79 ±0.51$^{**(b)}$	8.78 ±0.85$^{**(b)}$	22.72 ±2.69$^{**(b)}$
GP_5	6.74 ±0.36$^{**(b)}$	16.36 ±1.38$^{**(b)}$	6.21 ±0.48$^{**(b)}$	0.55 ±0.39$^{**(b)}$	12.35 ±0.31$^{**(b)}$	19.60 ±1.58$^{**(b)}$

GP_1- Normal; **GP_2**- Lithiatic Control; **GP_3**- NVK (100mg/kg);**GP_4**- NVK (200mg/kg); **GP5**-Cystone herbal tablets (100mg/kg)

- Values are expressed as mean ± SEM
- Values were found out by using ONE WAY ANOVA Followed by Newman keul's multiple range tests.
- **(a) Values were significantly different from normal control (GP_1) at P< 0.01
- **(b) Values were significantly different from Lithiatic control (GP_2) at P<0.01

The above table no.4 showed the siddha poly herbal formulation NERUNJI VER KUDINEER had significant (p<0.01) LITHOTRIPTIC activity as compare to normal control animals.

5.1.4.2. DIURETIC ACTIVITY OF NERUNJI VER KUDINEER

Table:1 Diuretic activity of NERUNJI VER KUDINEER

Group	Treatment	Urine Volume
I	Normal saline 10ml/kg	8.15±0.50
II	Frusemide 20mg/kg	12.85±0.90**
III	Nerunjiver Kudineer100mg/kg	11.15±0.65**
IV	Nerunjiver Kudineer200mg/kg	12.40±0.90**

Table 2: Natriuretic activity of NERUNJI VER KUDINEER

Treatment	Na+	K+	Na+/K+
Normal saline 10ml/kg	1.75±0.12	0.75±0.04	2.33
Frusemide 20mg/kg	3.28±0.26**	0.90±0.07**	3.64
Nerunjiver Kudineer100mg/kg	1.96±0.17*	0.71±0.01ns	2.76
Nerunjiver Kudineer200mg/kg	2.28±0.20**	0.69±0.02ns	3.30

Values are Mean ± SEM, n=6, *p<0.05, **p<0.01, NS - not significant

Conclusion

From the above table no 1 & 2, it is concluded that Nerunji Ver Kudineer used by Siddha preparation traditionally showed **significant diuretic activity**. The experimental evidence obtained in the laboratory model could provide a rationale for the traditional use of this siddha preparation as diuretic.

5.1.4.3 Evaluation of Analgesic Activity of Nerunji Ver Kudineer in Animal Models

Table 1. Effects of siddha formulation Nerunji Ver Kudineer on acetic acid–induced writhing response (N=6 in each group).

Groups	Treatment	(number of writhing movements) (Mean ± S.E)	Percentage %
Group I	Distilled water	34.15 ± 2.78	
Group II	Diclofenac sodium 10mg/kg	6.38 ± 0.74*b	81.31%
Group III	100mg/kg Nerunji ver Kudineer	14.08 ± 1.68*b	58.77%
Group IV	200mg/kg Nerunji Ver Kudineer	13.15 ± 1.34*b	61.49%

- Values are expressed as mean **±** SEM.

* (b) Values are significantly different from Toxic control G2 at $P<0.01$

CONCLUSION:

It can be concluded that possesses anti-nociceptive properties which are probably mediated via inhibition of prostaglandin synthesis as well as central inhibitory mechanisms which may be of potential benefit for the management of pain and inflammatory disorders.

5.1.5. TOXICITY STUDY OF NERUNJI VER KUDINEER

TABLE. 1. ACUTE TOXICITY STUDY OF NERUNJI VER KUDINEER

	Dose ($mg.kg^{-1}$)	Sign of Toxicity ($ST.NB^{-1}$)	Mortality ($D.S^{-1}$)
Group I	0	0/3	0/3
Group II	300	0/3	0/3
Group III	2000	0/3	0/3

The acute toxicity of Nerunji ver kudineer on experimental mice was tested using OECD-423 guidelines, where ST- sign of toxicity; NB- normal behaviour; D-died; S- survive. Values are expressed as number of animals (n=3).

B.Effect of NERUNJI VER KUDINEER in subchronic toxicity

Table.2. Effect of Nerunji ver kudineer on body weight changes in rats:

Treatment	Day 1	Day 5	Day 10	Day 20
Control	185.25±6.11	187.47 ±6.25	196.15 ±6.40	196.7±6.60
Nerunji ver kudineer **50 mg.kg^{-1}**	194.35 ±6.4	193.35 ±6.35	198.25 ±6.70	198.30±6.75*
Nerunji ver kudineer **100 mg.kg^{-1}**	186.40 ±5.7	189.35 ±6.45	196.55 ±7.10	197.36±6.33*
Nerunji ver kudineer **200 mg.kg^{-1}**	195.35 ±7.2	198.20±6.55	198.90 ±7.20**	206.45±7.31**
Nerunji ver kudineer **400 mg.kg^{-1}**	187.70 ±6.05	192.15 ±5.65	195.60 ±6.35**	207.66±7438**

The effect of NVK was observed for their effect on the body weight changes from the study it was observed that, there was significant increase ($p<0.05$) in body weight in all the animals observed.

C.Effect of Nerunji ver kudineer on kidney, heart, liver and brain in rats

The effects of **Nerunji ver kudineer** on kidney, heart, liver and brain of the rats were observed. ***From the study it was clear that, significant (p<0.01) changes in the weights of various organs of the animals occurred with higher doses of the extract (400 mg.kg^{-1} bwt), but macroscopic examinations did not show any changes in colour of the organs of the treated animals compared with the control***. The results are shown below table no.3

Table no.3.Effect of NVK on kidney, liver, heart and brain in rats

Treatment	Heart (gms)	Kidney (gms)	Liver (gms)	Brain (gms)
Control	0.36 ± 0.07	0.66± 0.05	3.34± 0.07	0.67± 0.75
Nerunjiver kudineer@50 mg.kg^{-1}	0.37± 0.04	0.82± 0.05	3.44± 0.05	0.70± 0.5
Nerunjiver kudineer@100 mg.kg^{-1}	0.38± 0.08	0.80± 0.06	3.36±0.04	0.68± 0.4
Nerunjiver kudineer@ 200 mg.kg^{-1}	0.37± 0.06	0.75± 0.04	3.34± 0.04	0.75± 0.07
Nerunjiver kudineer@400 mg.kg^{-1}	0.36± 0.05	0.76± 0.05	3.37± 0.05	0.77± 0.07

D.Effect of NVK on biochemical profiles of rats

The effect of **NVK** on various biochemical parameters of the experimental animal 'rats' were tested. From the study it was evident that, there was significant decrease ($p<0.05$) in the plasma glucose level in treated rats especially at higher dose (400 $mg.kg^{-1}$) compared with control rats. The control rats were administered only with 5 ml of normal saline. Significant decrease ($p<0.05$) in the plasma total cholesterol (TC), triglyceride (TG) and LDL-cholesterol levels were observed. But a significant increase ($p<0.05$) in HDL-cholesterol levels were observed in all the treated animals compared with the control animals. AST, ALT and ALP levels were also normal in the **NVK** treated animals. From the results of biochemical study there was no evidence of severe toxicity associated with the administration of higher concentration of **NVK**. The results are shown in Table no.4.

Table no.4.Effect of NVK on biochemical profiles of rats

Treatment	**AST ($IU.l^{-1}$)**	**ALT ($IU.l^{-1}$)**	**ALP ($IU.l^{-1}$)**	**TP ($g.l^{-1}$)**	**ALBUMIN ($g.l^{-1}$)**
Control	328.5±12.40	71.5± 3.18	253.58± 8.80	69.85± 3.32	39.15±2.35
Nerunji ver kudineer@50 $mg.kg^{-1}$	317.0±9.50**	69.5± 2.20**	266.10± 2.75**	70.30± 2.32	36.30±2.65
Nerunji ver kudineer@ 100 $mg.kg^{-1}$	318.3±7.20**	67.1± 3.15**	260.18± 6.70**	80.15± 2.82	38.30±3.05
Nerunji ver kudineer@ 200 $mg.kg^{-1}$	313.4±7.95	64.4± 2.90	265.00± 5.20	69.25± 3.32	40.20±2.75
Nerunji ver kudineer@ 400 $mg.kg^{-1}$	323.2± 8.20	64.3± 3.52	269.40± 4.40	74.05± 2.58	39.48±2.70

E.Effect of Nerunji ver kudineer on haematological parameters in rats

The effects of **Nerunji ver kudineer** were observed for its effect on haematological parameters on the experimental rats. From the study it was evident that, a significant increase ($p<0.01$) were observed in the haemoglobin contents and RBC count in the group treated with 200 $mg.kg^{-1}$ body weight of **Nerunji ver kudineer** and a significant decrease of the parameters occurred in the group treated with 400 $mg.kg^{-1}$ b.w.t compared with the control. There was no significant change in the calcium level in all the treated animals compared to the control.

Table no.5. Effect of NVK on haematological parameters in rats

Treatment	Haemoglobin ($mg.dl^{-1}$)	RBC (10^6 /mm^3)	WBC (10^6 /mm^3)	Calcium ($mg.dl^{-1}$)
Control	**13.35± 0.27**	**9.15± 0.02**	**11.45± 0.05**	**9.45 ±0.02**
Nerunji ver kudineer@ 50 $mg.kg^{-1}$	**14.55± 0.28***	**9.50± 0.04***	**9.55± 0.01***	**9.33 ±0.02**
Nerunji ver kudineer@ 100 $mg.kg^{-1}$	**14.35± 07***	**9.55± 0.02***	**8.35± 0.32***	**9.21±0.20**
Nerunji ver kudineer@ 200 $mg.kg^{-1}$	**12.75± 0.22***	**8.33± 0.12***	**11.45± 0.03***	**9.51 ±0.13**
Nerunji ver kudineer@ 400 $mg.kg^{-1}$	**13.5± 0.35***	**8.46± 0.45***	**10.5± 0.13***	**9.73 ±0.02**

The overall results suggest that Nerunji ver kudineer are non toxic to the haaematopoietic and leucopoietic system. The haematopoietic and leucopoietic systems are the most sensitive targets for toxic compounds and an important index of physiological and pathological status in man and animal (Adeneye, *et al*., 2006).(13) Therefore, it is possible to assume that the Nerunji ver kudineer is non haematotoxic.

Discussion

The acute toxicity study of *Nerunji ver kudineer* was carried out as per OECD-423 guidelines, no mortality was observed in both the animals of control group as well as animals treated with a maximum dose of 2000 $mg.kg^{-1}$. Hence, in subchronic toxicity started from 200 $mg.kg^{-1}$ of dose as per $1/10^{th}$ of 2000 $mg.kg^{-1}$ of acute dose i.e. hasn't shown any abserved mortality during the period of study. There was no significant change in animal behaviour due to the absence of toxicity. Hence, this can be concluded that, the ***Nerunji ver Kudineer*** has been taken as per the standard dosing protocol for the beneficial effect for suitable clinical conditions.

5. 2 .CLINICAL STUDY

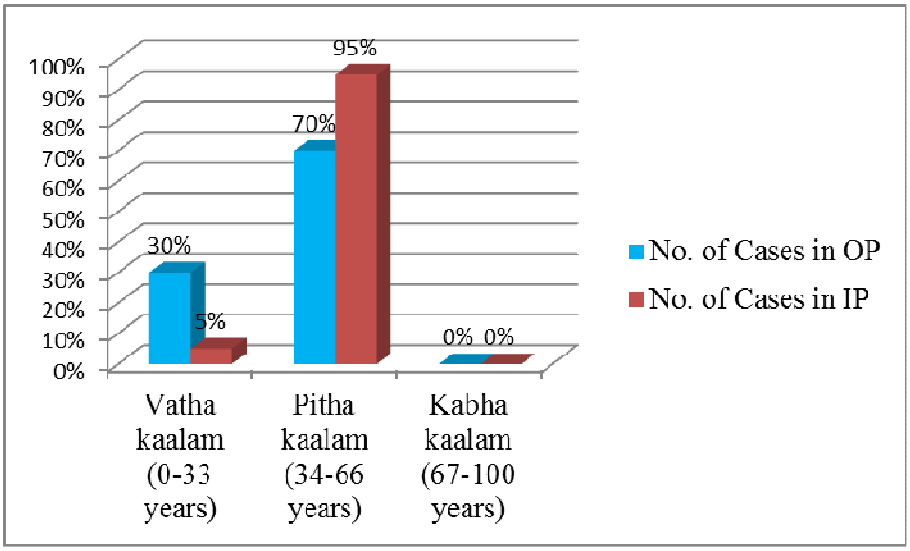
The results obtained from the presence study were recorded in the proforma with respect to the following parameters for each patient both out-patients and in-patients. They were analysed statistically in order to arrive at the percentage composition.

1. Age (Kaalam) Distribution
2. Gender Distribution
3. Occupational Status
4. Dietary Habits
5. Marital Status
6. Personal Habits
7. Paruvakaalam (Season)
8. Thinai (Land)
9. Thegathathuvam (Thegi)
10. Manothathuvam (Gunam)
11. Uyir Thathukal
    a) Derangement of Vatham
    b) Derangement of Pitham
    c) Derangement of Kabam
12. Udal Thathukal
13. Kosangal
14. 14 Vegangal
15. Envagai Thervugal
16. Neerkuri
17. Neikuri
18. Duration of Illness
19. Number of Stones
20. Position of Stones
21. Size of Stones
22. Urolithiasis Symptoms Score
23. Grading outcomes of the study

Table 1 : AGE DISTRIBUTION

sl no	Age	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	Vatha kaalam (0-33 years)	6	30%	1	5%
2	Pitha kaalam (34-66 years)	14	70%	19	95%
3	Kabha kaalam (67-100 years)	0	0%	0	0%

Figure 1 : AGE DISTRIBUTION



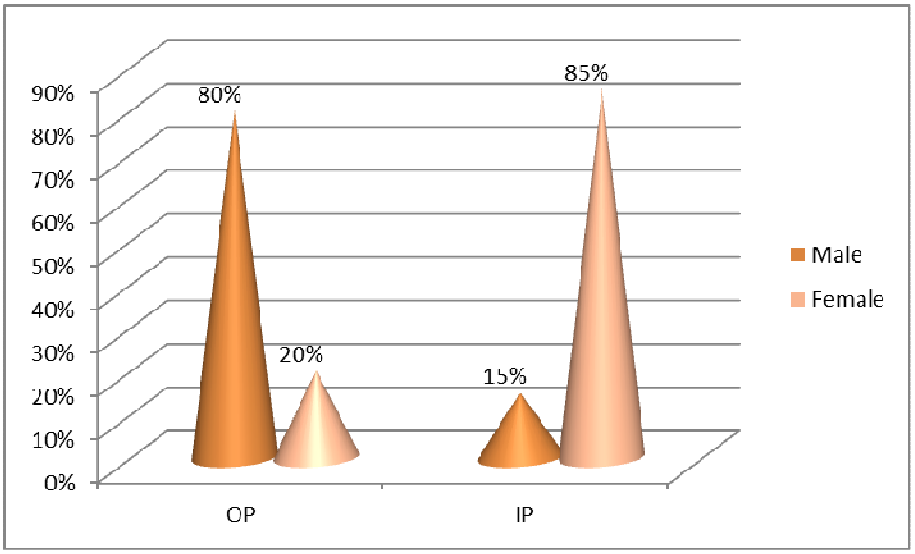
Inference:

The above table reveals that majority of both out patients 70% and in patients 95% comes under Pitha kaalam, 30% of outpatients and 5% of inpatients comes under Vatha kaalam.

Table 2 : GENDER DISTRIBUTION

S.no	Gender	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	Male	16	80%	3	15%
2	Female	4	20%	17	85%

Figure 2 : GENDER DITRIBUTION



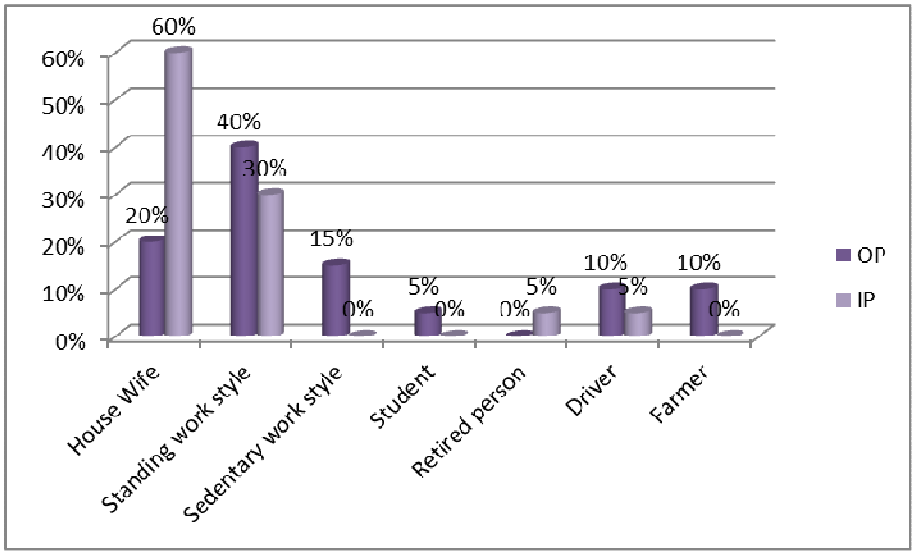
Inference:

From the above table, out patients Male 80% and Female 20% were affected. And inpatients 15% were Male and 85% were Female affected.

Table 3 : OCCUPATIONAL STATUS

sl no	Occupation	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	House Wife	4	20%	12	60%
2	Standing work style	8	40%	6	30%
3	Sedentary work style	3	15%	0	0%
4	Student	1	5%	0	0%
5	Retired person	0	0%	1	5%
6	Driver	2	10%	1	5%
7	Farmer	2	10%	0	0%

Figure 3 : OCCUPATIONAL STATUS



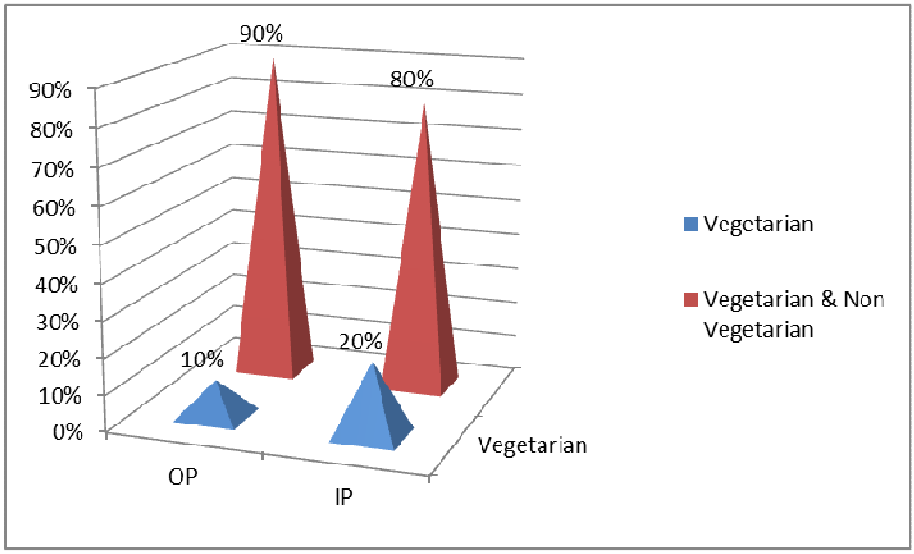
Inference:

Among out patients majority of them are standing workers 40%, compared to otheir Works. Among in patients majority of them are house wives 60%, compared to other Works.

Table 4 : DIETARY HABITS

sl no	Diet	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	Vegetarian	2	10%	4	20%
2	Vegetarian & Non Vegetarian	18	90%	16	80%

Figure 4 : DIETARY HABITS



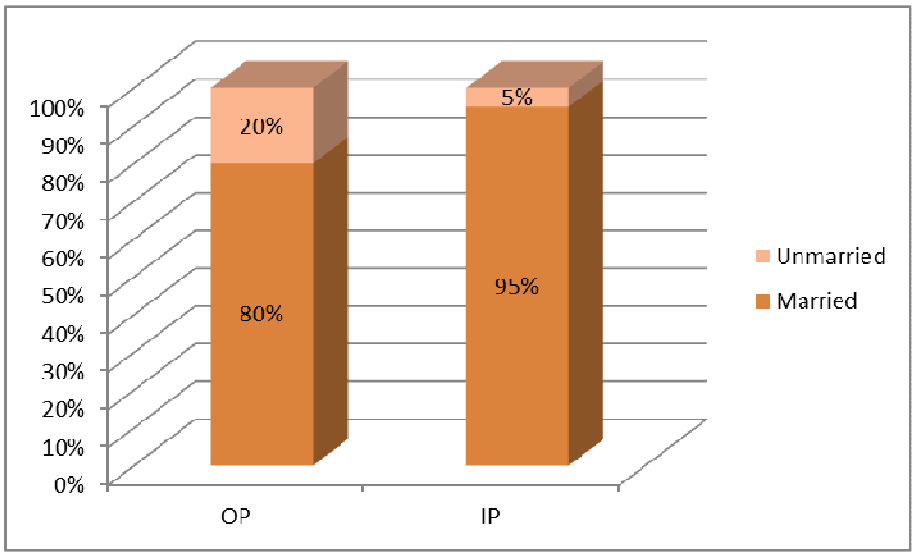
Inference:

This table reveals that majority of out patients 90% and in patients 80%, were both Vegetarian and Non- Vegetarian, compared to pure Vegetarian.

Table 5 : MARITAL STATUS

sl no	Marital	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	Married	16	80%	19	95%
2	Unmarried	4	20%	1	05%

Figure 5 : MARITAL STATUS



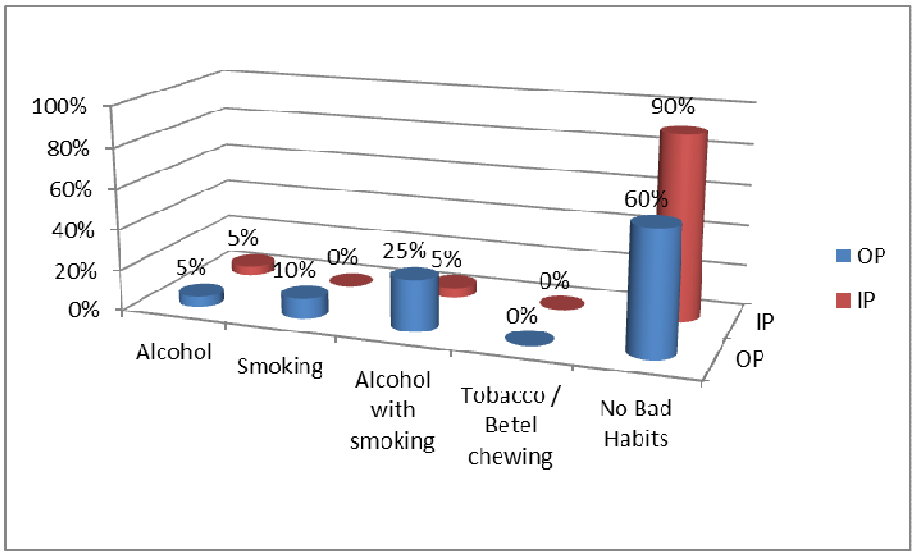
Inference:

This table reveals that majority of cases in out patients 80% and in patients 95% were Married, compared to Unmarried.

Table 6 : PERSONAL HABITS

sl no	Habits	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	Alcohol	1	5%	1	5%
2	Smoking	2	10%	0	0%
3	Alcohol with smoking	5	25%	1	5%
4	Tobacco / Betel chewing	0	0%	0	0%
5	No Bad Habits	12	60%	18	90%

Figure 6 : PERSONAL HABITS



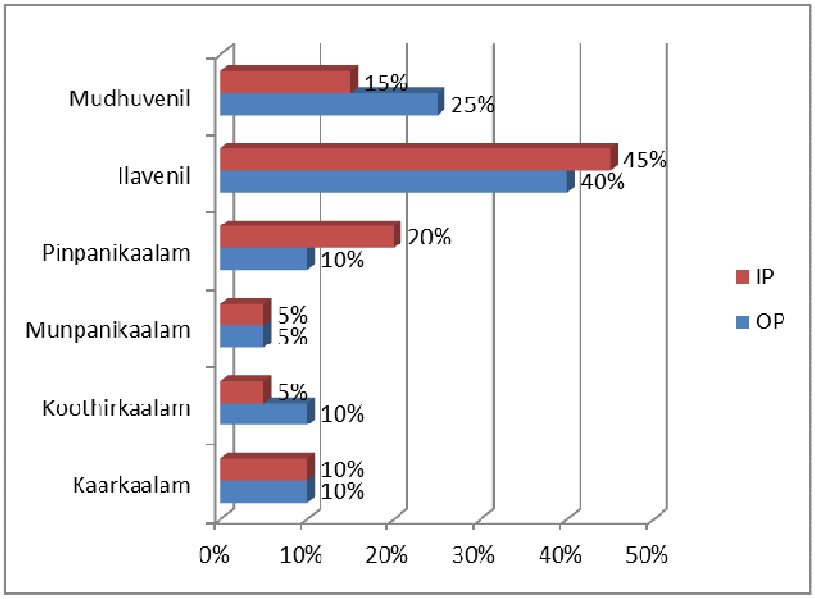
Inference:

This table reveals that majority of them out patients 60% and in patients 90% does not have Bad Habits, compared to other Bad Habits.

Table 7 : PARUVAKAALAM (SEASON)

sl no	Paruvakaalam	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	Kaarkaalam	2	10%	2	10%
2	Koothirkaalam	2	10%	1	5%
3	Munpanikaalam	1	5%	1	5%
4	Pinpanikaalam	2	10%	4	20%
5	Ilavenil	8	40%	9	45%
6	Mudhuvenil	5	25%	3	15%

Figure 7 : PARUVAKAALAM (SEASON)



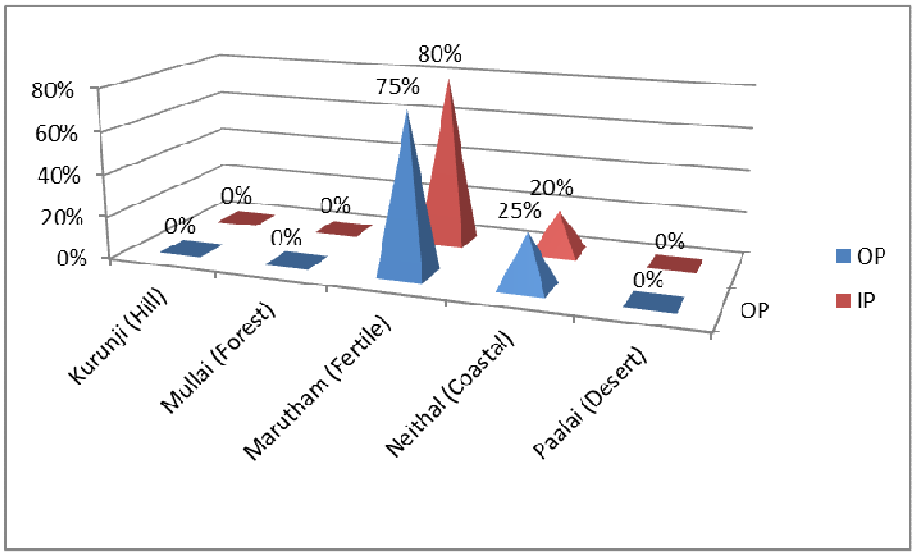
Inference:

Among out patients,majority of them were Ilavenil Kaalam40% and mudhuvenil 25%. And in patients, majority of them were Ilavenil Kaalam 45% and also Pinpani Kaalam 20%.

Table 8 : THINAI (LAND)

sl no	Thinai	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	Kurunji (Hill)	0	0%	0	0%
2	Mullai (Forest)	0	0%	0	0%
3	Marutham (Fertile)	15	75%	16	80%
4	Neithal (Coastal)	5	25%	4	20%
5	Paalai (Desert)	0	0%	0	0%

Figure 8 : THINAI (LAND)



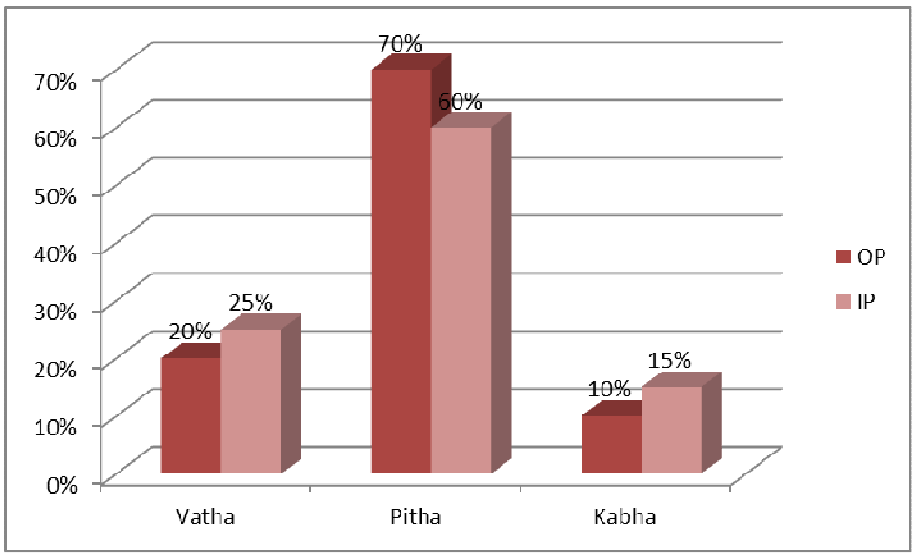
Inference:

Among out patients, 75% were Marutham, 25% were Neithal Among in patients, 80% were Marutham, 20% were Neithal.

Table 9 : THEGA THATHUVAM

Sl no	Thegi	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	Vatha	4	20%	5	25%
2	Pitha	14	70%	12	60%
3	Kabha	2	10%	3	15%

Figure 9 : THEGA THATHUVAM



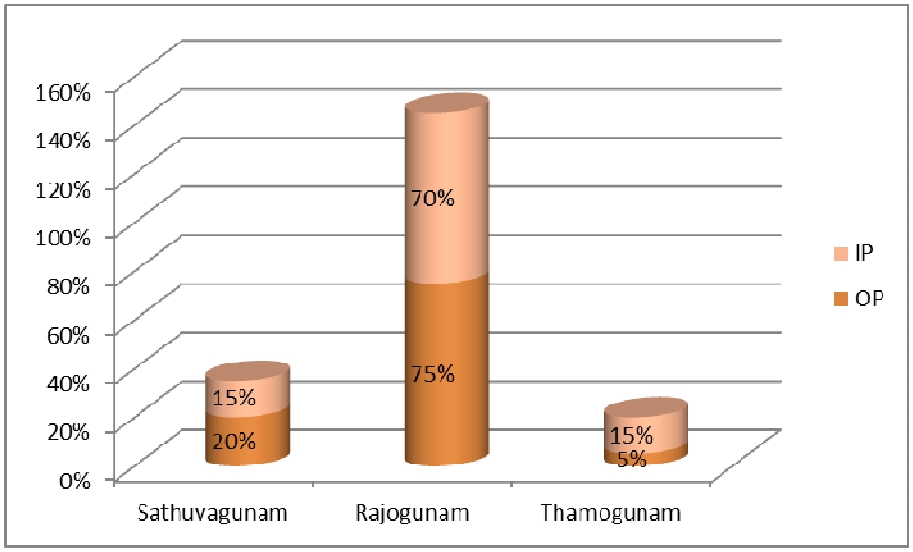
Inference:

Among out patients, 20% were Vatha Thegi, 70% were Pitha Thegi, 10% were Kabha Thegi. Among in patients, 25% were Vatha Thegi, 60% were Pitha Thegi, 15% were Kabha Thegi.

Table 10 : MANO THATHUVAM (GUNAM)

Sl no	Gunam	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	Sathuvagunam	4	20%	3	15%
2	Rajogunam	15	75%	14	70%
3	Thamogunam	1	5%	3	15%

Figure 10 : MANO THATHUVAM (GUNAM)



Inference:

Among out patients, 75% were Rajogunam, 20% were Sathuvagunam, 5% were Thamogunam.

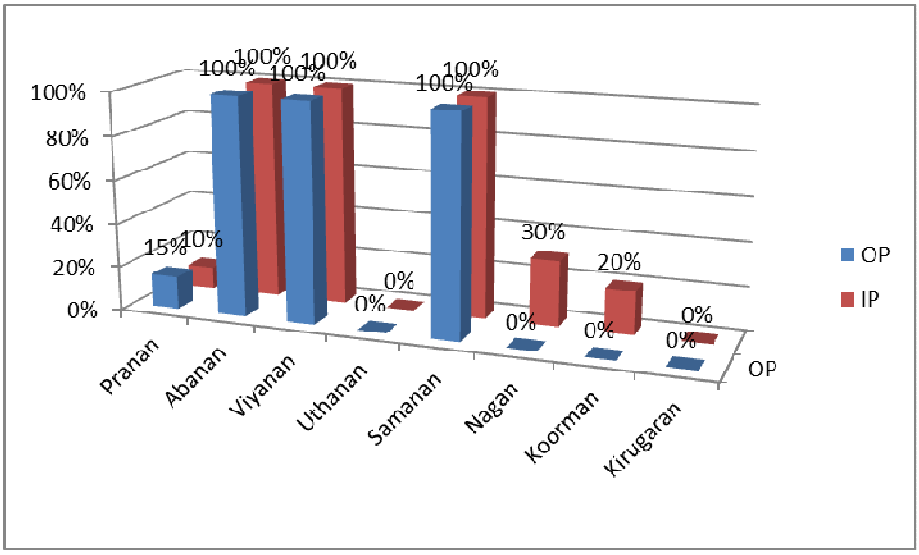
Among in patients, 70% were Rajogunam, 15% were Sathuvagunam, 15% were Thamogunam.

Table 11 : UYIR THATHUKAL

A) Derangement of Vatham

Sl no	Vatham	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	Pranan	3	15%	2	10%
2	Abanan	20	100%	20	100%
3	Viyanan	20	100%	20	100%
4	Uthanan	0	0%	0	0%
5	Samanan	20	100%	20	100%
6	Nagan	0	0%	6	30%
7	Koorman	0	0%	4	20%
8	Kirugaran	0	0%	0	0%
9	Thevathathan	0	0%	0	0%
10	Thanajeyan	-	-	-	-

Figure 11 A : Derangement of Vatham



Inference:

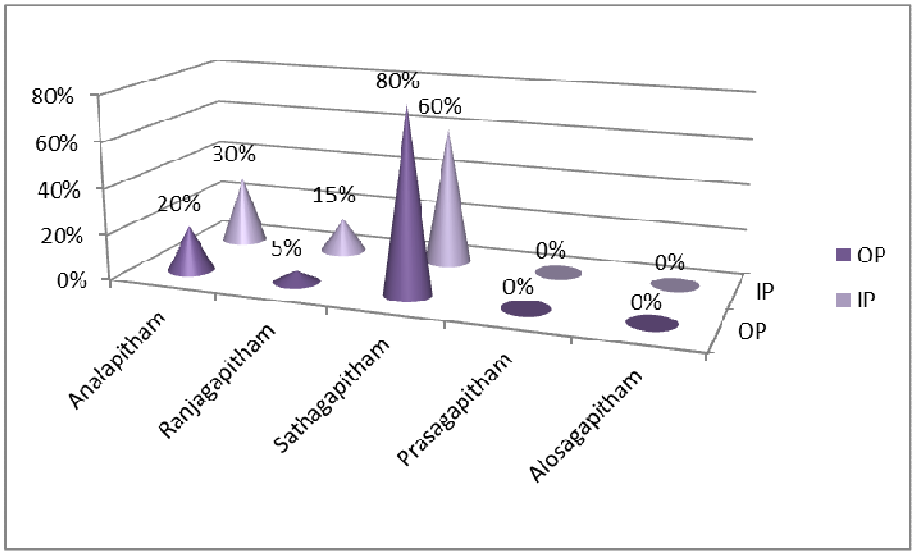
This table reveals that all the out patients and in patients have Derangement in Abanan Viyanan and Samanan Vayus 100% were affected, compared to other Vayus.

Table 11 : UYIR THATHUKAL

B) Derangement of Pitham

Sl no	Pitham	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	Analapitham	5	20%	6	30%
2	Ranjagapitham	1	5%	3	15%
3	Sathagapitham	16	80%	12	60%
4	Prasagapitham	0	0%	0	0%
5	Alosagapitham	0	0%	0	0%

Figure 11 B : Derangement of Pitham



Inference:

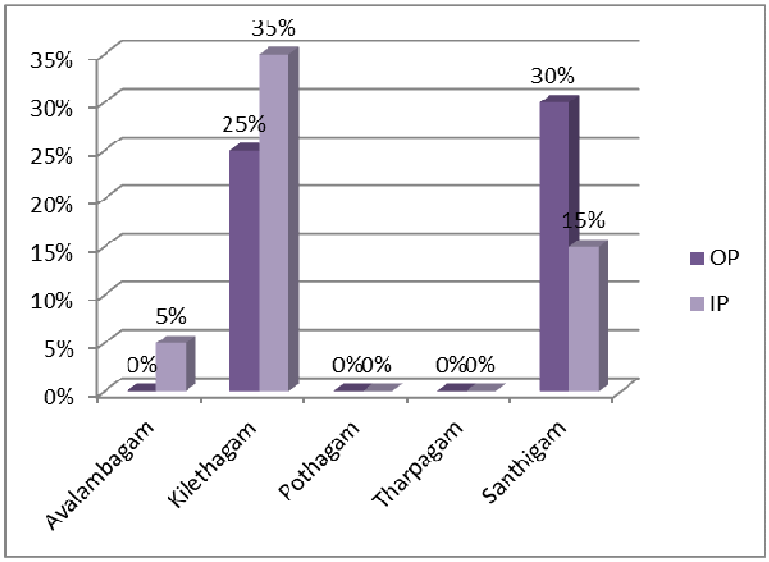
This table reveals that majority of the out patients 80% and in patients 60% were affected in Sathagapitham. And few cases affected Ranjagapitham and Analapitham.

Table 11 : UYIR THATHUKAL

C) Derangement of Kabam

Sl no	Kabam	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	Avalambagam	0	0%	1	5%
2	Kilethagam	5	25%	7	35%
3	Pothagam	0	0%	0	0%
4	Tharpagam	0	0%	0	0%
5	Santhigam	6	3O%	3	15%

Figure 11 C : Derangement of Kabam



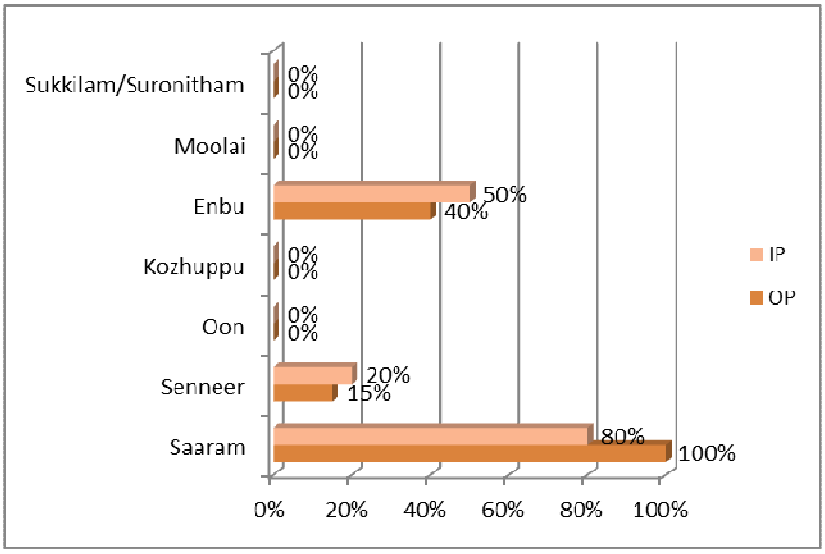
Inference:

This table reveals that majority of out patients 35% and in patients 25% was affected Kilethagam. And some patients were affected Avalambagam and santhigam.

Table 12 : UDAL THATHUKAL

Sl no	Udal Thathukal	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	Saaram	20	100%	16	80%
2	Senneer	3	15%	4	20%
3	Oon	0	0%	0	0%
4	Kozhuppu	0	0%	0	0%
5	Enbu	8	40%	10	50%
6	Moolai	0	0%	0	0%
7	Sukkilam / Suronitham	0	0%	0	0%

Figure 12 : UDAL THATHUKAL



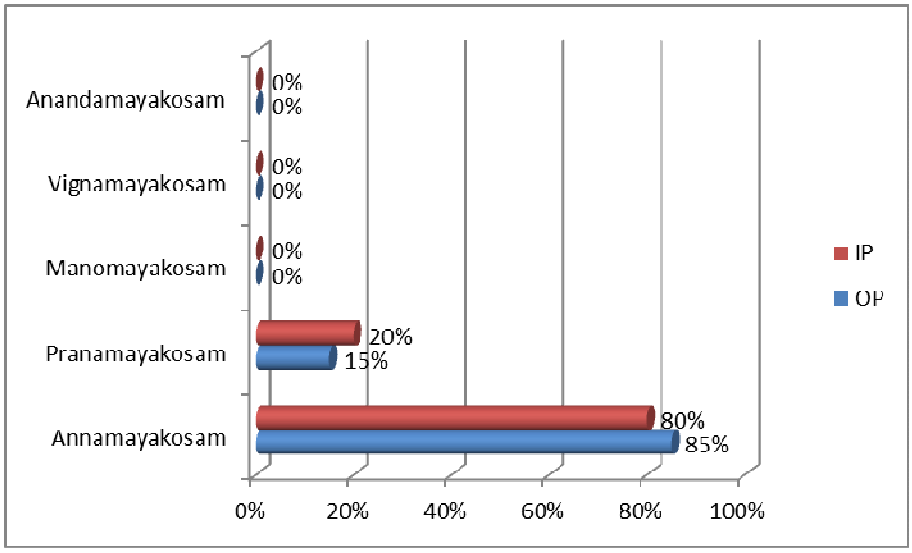
Inference:

The table no.12 reveals that majority of the out patients 100% and in patients 80% were affected by Saaram. And few cases were also affected by Enbu and Senneer.

Table 13 : KOSANGAL

Sl no	Kosangal	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	Annamayakosam	17	85%	16	80%
2	Pranamayakosam	3	15%	4	20%
3	Manomayakosam	0	0%	0	0%
4	Vignamayakosam	0	0%	0	0%
5	Anandamayakosam	0	0%	0	0%

Figure 13 : KOSANGAL



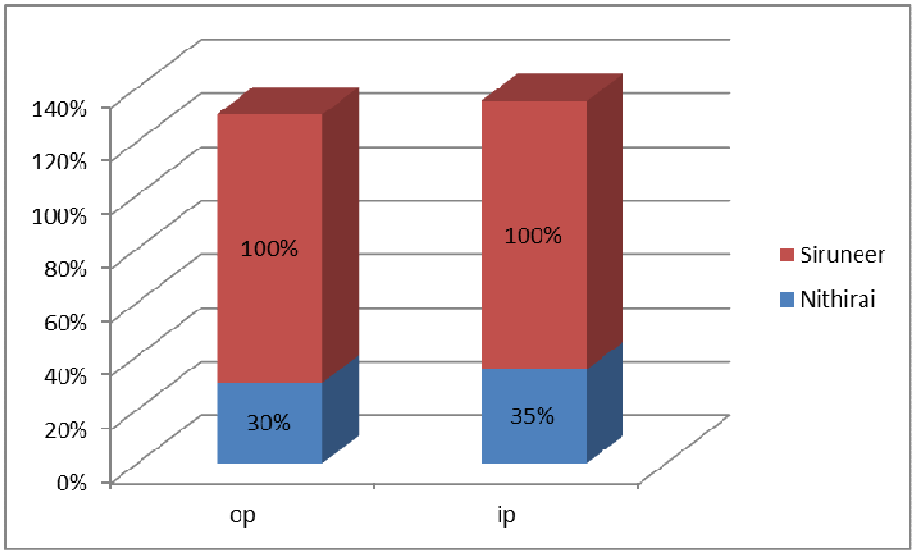
Inference:

This table reveals that majority of the out patients 85% and in patients 80% were affected by Annamayakosam. And few cases were affected by Pranamayakosam.

Table 14 : 14 VEGANGAL

Sl no	Vegangal	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	Nithirai	6	30%	7	35%
2	Siruneer	20	100%	20	100%

Figure 14 : 14 VEGANGAL



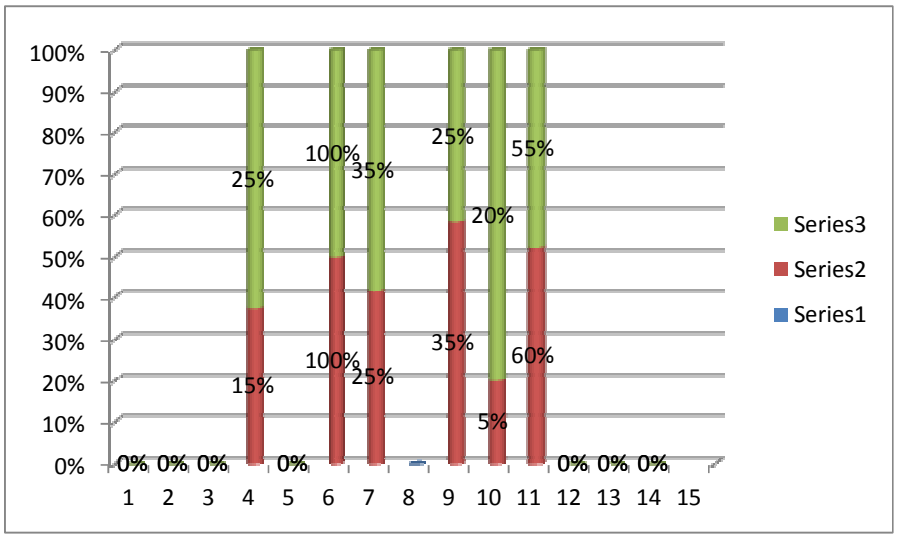
Inference:

This table reveals that majority of the out patients 100% and in patients 100% were affected by Siruneer. Few cases were affected by nithirai. And other vegangal were not affected.

Table 15 : ENVAGAI THERVUGAL

Sl no	Envagai Thervugal	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	Naa	0	0%	0	0%
2	Niram	0	0%	0	0%
3	Mozhi	0	0%	0	0%
4	Vizhi	3	15%	5	25%
5	Malam	0	0%	0	0%
6	Moothiram	20	100%	20	100%
7	Sparism	5	25%	07	35%
8	Naadi				
	a) Vathapitham	7	35%	5	25%
	b) Vathakabam	1	5%	4	20%
	c) Pithavatham	12	60%	11	55%
	d) Pithakabam	0	0%	0	0%
	e) Kathavatham	0	0%	0	0%
	f) Kabhapitham	0	0%	0	0%

Figure15: ENVAGAI THERVUGAL

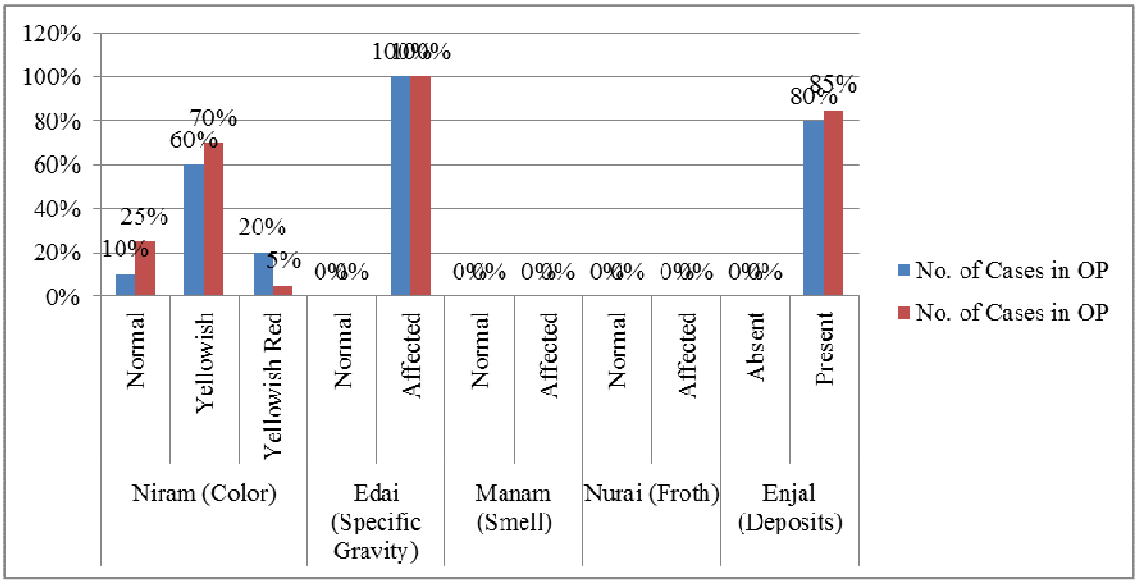


Inference: This table understood that majority of the out patients 100% and in patients 100% that Moothiram was affected. And majority of cases Pithavatha naadi was mostly observed.

Table 16 : NEERKURI

Sl no	Type of Test Result		Out patients		In patients	
			No. of Cases	Percentage	No. of Cases	Percentage
1	Niram (Color)	Normal	2	10%	5	25%
		Yellowish	14	60%	14	70%
		Yellowish Red	4	20%	1	5%
2	Edai (Specific Gravity)	Normal	0	0%	0	0%
		Affected	20	100%	20	100%
3	Manam (Smell)	Normal	0	0%	0	0%
		Affected	0	0%	0	0%
4	Nurai (Froth)	Normal	0	0%	0	0%
		Affected	0	0%	0	0%
5	Enjal (Deposits)	Absent	0	0%	0	0%
		Present	16	80%	17	85%

Figure 16 : NEERKURI



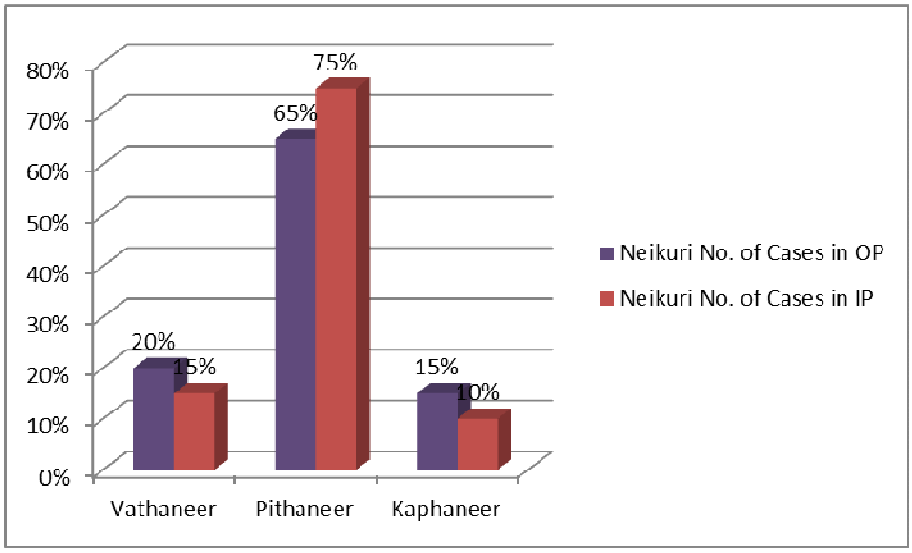
Inference:

Majority of patients have Yellowish Urine. All patients 100% were affected by Edai i.e Specific gravity. Enjal are also present in many patients.

Table 17 : NEIKURI

Sl no	Neikuri	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	Vathaneer	4	20%	3	15%
2	Pithaneer	13	65%	15	75%
3	Kaphaneer	3	15%	2	10%

Figure 17 : NEIKURI



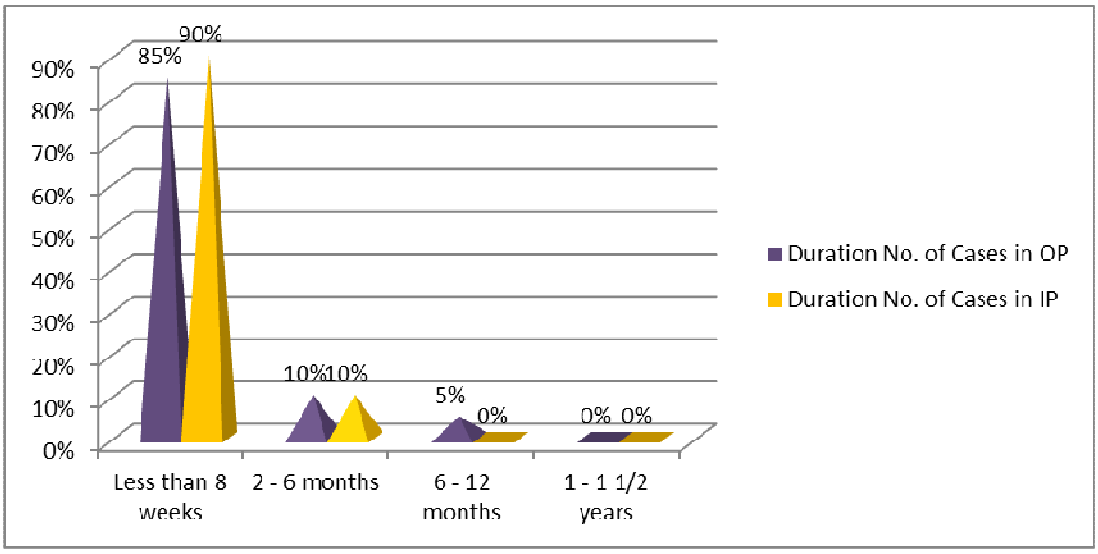
Inference:

Majority of the patients, have Pitha Neer (65% out patients and 75% in patients), and then Vatha Neer (20% out patients and 15% in patients), and also in few patients Kabha neer found.

Table 18 : DURATION OF ILLNESS

Sl no	Duration	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	Less than 8 weeks	17	85%	18	90%
2	2 - 6 months	2	10%	2	10%
3	6 - 12 months	1	5%	0	0%
4	1 - 1 1/2 years	0	0%	0	0%

Figure 18 : DURATION OF ILLNESS



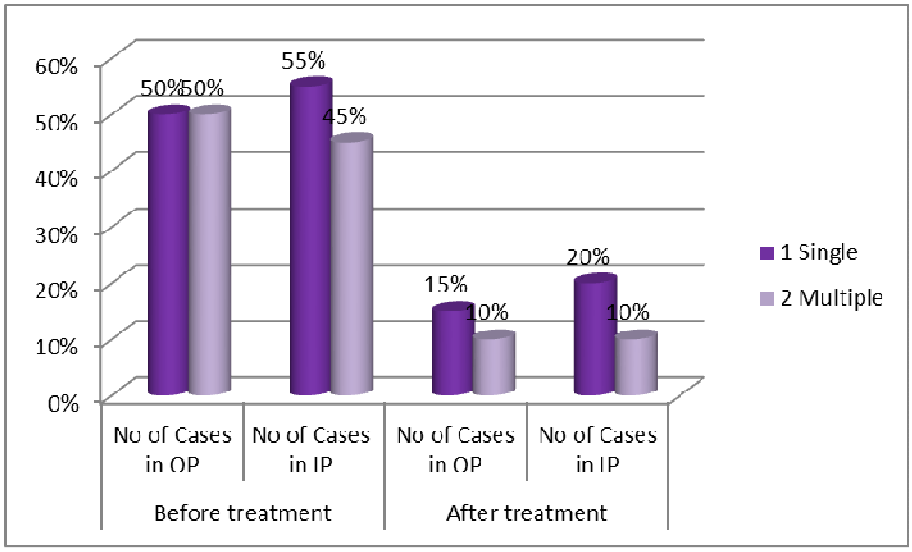
Inference:

During the time of period less than 8 weeks and have majority of out patients. During the time of period less than 8 weeks have majority of in patients.And 2-6 months have few patients.

Table 19 : NUMBER OF STONES

Sl no	No. of Stones	Before Treatment				After Treatment			
		Out patients		In patients		Out patients		In patients	
		No of Cases	Percentage	No of Cases	Percentage	No of Cases	Percentage	No of Cases	Percentage
1	Single	10	50%	11	55%	3	15%	4	20%
2	Multiple	10	50%	9	45%	2	10%	2	10%

Figure 19 : NUMBER OF STONES



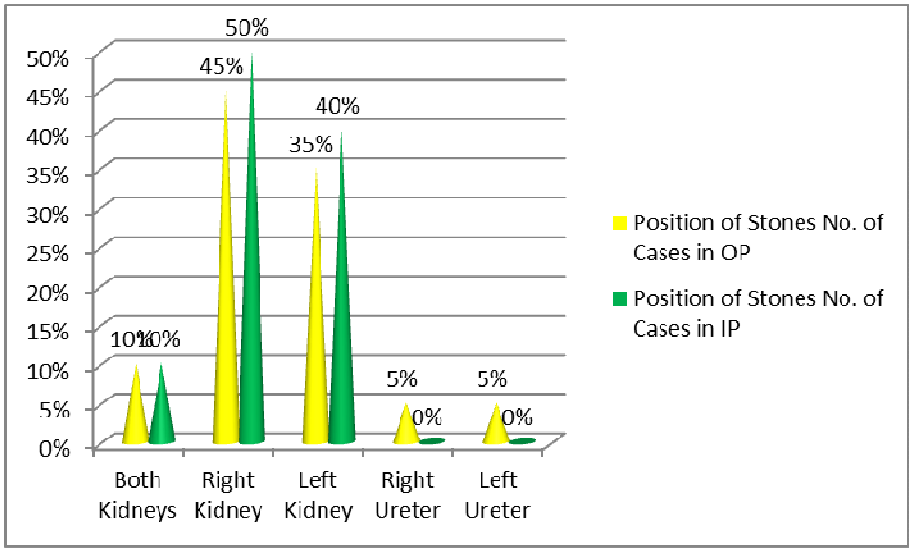
Inference:

This table reveals, before treatment majority of the(50% out and 50% in patients) has Single stone, and few cases has Multiple stones. But after treatment (15% out and 20% in patients) were Single stone, and few were Multiple stones.

Table 20 : POSITION OF STONES IN URINARY SYSTEM

Sl no	Position of Stones	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	Both Kidneys	2	10%	2	10%
2	Right Kidney	9	45%	10	50%
3	Left Kidney	7	35%	8	40%
4	Right Ureter	1	5%	0	0%
5	Left Ureter	1	5%	0	0%

Figure 20 : POSITION OF STONES IN URINARY SYSTEM



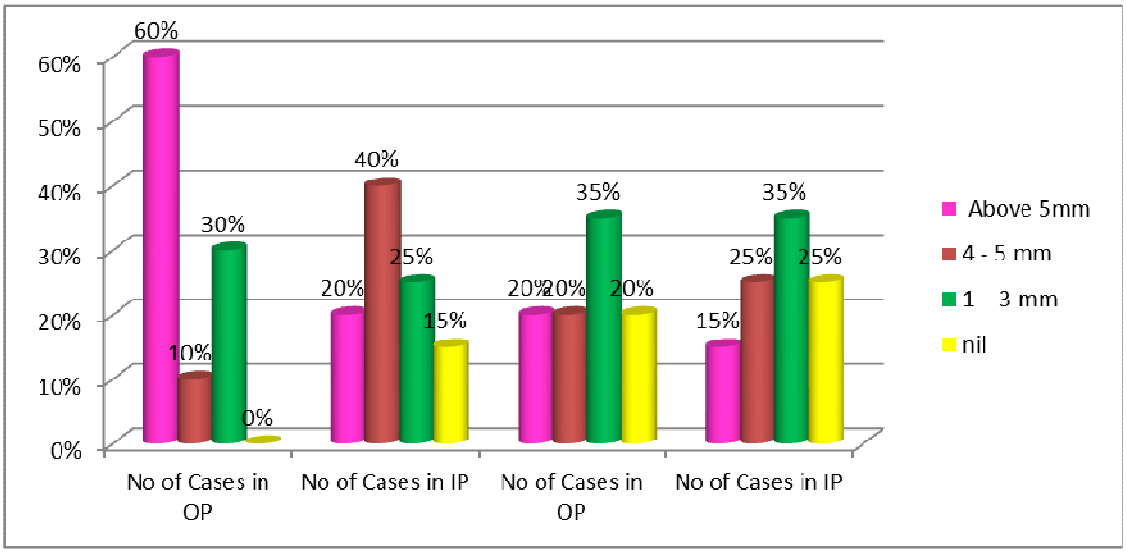
Inference:

Majority of cases of out patients 50% has calculi in Right Kidney . And also in patients 35% has calculi in Left Kidney.

Table 21 : SIZE OF STONES

sl no	Size of Stones	Before Treatment				After Treatment			
		Out patients		In patients		Out patients		In patients	
		No of Cases	Percentage	No of Cases	Percentage	No of Cases	Percentage	No of Cases	Percentage
1	Above 5mm	12	60%	4	20%	4	20%	3	15%
2	4 - 5 mm	2	10%	8	40%	5	20%	5	25%
3	1 – 3 mm	6	30%	5	25%	7	35%	7	35%
4	nil	0	0%	3	15%	4	20%	5	25%

Fig 21 : SIZE OF STONES



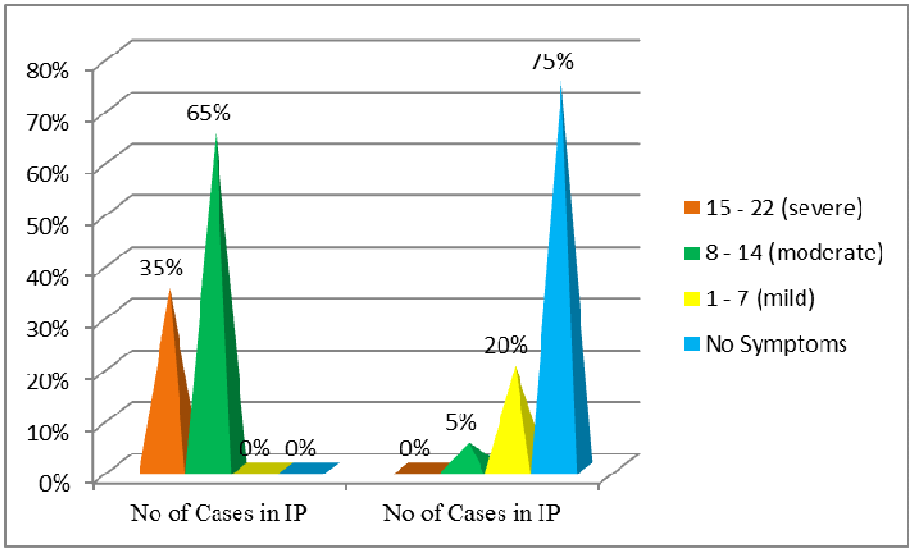
Inference

Before treatment, the USG reports of majority of cases, stone size will be 5mm and above , and 1-3mm in second major cases. After treatment majority of the cases, stone size will be upto <3mm. Thus the drug will be reduce the stone size. P<0.0001 was considered statistically significant difference.

Table 22 : UROLITHIASIS SYMPTOMS SCORE

Sl no	Types of score	Before				After			
		Out patients		In patients		Out patients		In patients	
		No of Cases	Percentage	No of Cases	Percentage	No of Cases	Percentage	No of Cases	Percentage
1	15 - 22 (severe)	5	25%	7	35%	0	0%	0	0%
2	8 - 14 (moderate)	12	60%	13	65%	3	15%	1	5%
3	1 - 7 (mild)	3	15%	0	0%	3	15%	4	20%
4	No Symptoms	0	0%	0	0%	14	70%	15	75%

Figure 22 : UROLITHIASIS SYMPTOMS SCORE



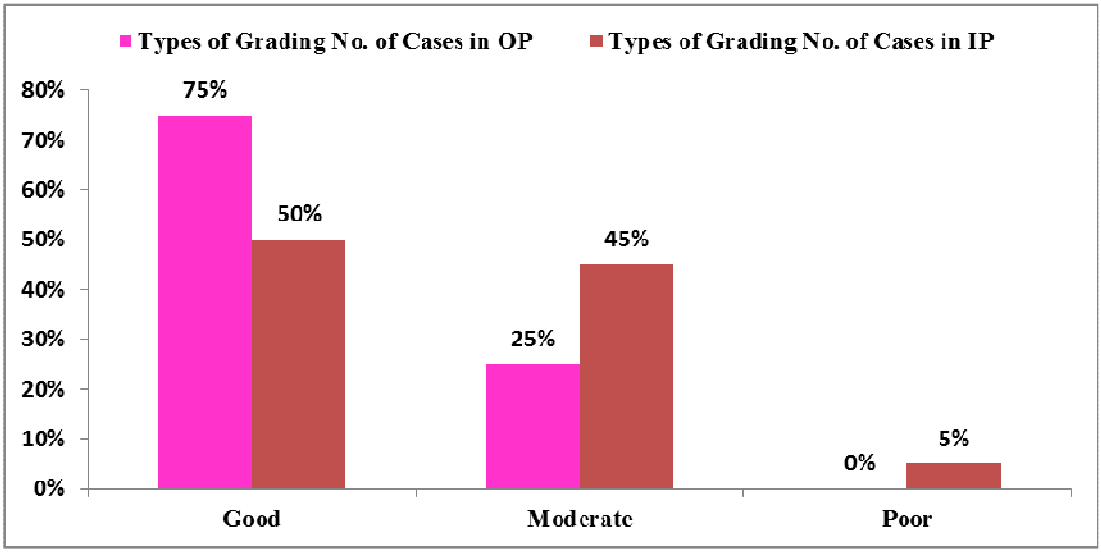
Inference:

The above table resembles that the score will be severe (out patients 35% and in patients 35%). And moderate in (60% of out patients and 65% of in patients),. Hence the score will be gradually decreased during treatment. And finally after the study (70% of out patients and 75% of in patients) have no symptoms. P<0.0001 was considered statistically significant difference.

Table 23 : GRADING OUTCOMES OF THE STUDY

Sl no	Types of Grading	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	Good	15	75%	10	50%
2	Moderate	5	25%	9	45%
3	Poor	0	0%	1	5%

Figure 23 : GRADING OUTCOMES OF THE STUDY



Inference:

From the above table that majority of (out patients 75% and in patients 50%) have good response. Moderate response were observed in (25% of out patients and 45% of in patients). Thus the trial drug is very effective in curing kalladaippu noi.

Table 24 : Statistical Analaysis:

Parameters	**Treatment**	**Mean**	**Standard Deviation**	**"t" value**	**P value**
Size of Stone (mm)	BT	6.5375	5.45540	4.873	**< 0.0001**
	AT	2.7750	3.60190		
Urolithiasis Symptom Score	BT	12.4000	4.17440	3.065	**< 0.0001**
	AT	1.7250	3.55894		

CASE SHEET OF 20 OUT PATIENTS TREATED FOR KALLADAIPPU NOI

S. No	Op. No	Name	Age	Sex	Starting Of Treatment	End of treatment	No Of Days Treated	Result
1.	44662	Karthick	26	M	22/05/2018	21/06/2018	30 Days	Fair
2.	44701	Saraswathi	36	F	22/05/2018	21/06/2018	30 Days	Fair
3.	45298	Annamalai	33	M	24/05/2018	23/06/2018	30 Days	Fair
4.	47187	Lakshmi Arun	35	M	31/05/2018	29/06/2018	30 Days	Good
5.	50375	Ponraj	31	M	13/06/2018	11/07/2018	30 Days	Fair
6.	55421	Buharisherif	46	M	02/07/2018	31/07/2018	30 Days	Good
7.	55935	Shanthi	50	F	04/07/2018	03/08/2018	30 Days	Good
8.	56318	Venkatachalam	44	M	05/07/2018	04/08/2018	30 Days	Fair
9.	58900	Marimuthu	26	M	14/07/2018	13/08/2018	30 Days	Fair
10.	58928	Gunasekaran	60	M	14/07/2018	13/08/2018	30 Days	Fair
11.	78755	Sivakumar	37	M	22/09/2018	20/10/2018	30 Days	Fair
12.	77895	Rakesh	19	M	19/09/2018	17/10/2018	30 Days	Good
13.	104995	Subbaiah	36	M	23/11/2018	21/12/2018	30 Days	Good
14.	103629	Raja	25	M	14/12/2018	14/01/2019	30 Days	Good
15.	103830	Joseph	28	M	15/12/2018	13/01/2019	30 Days	Fair
16.	105355	Murugammal	38	F	20/12/2018	19/01/2019	30 Days	Fair
17.	105373	Pushpam	43	F	20/12/2018	19/01/2019	30 Days	Good
18.	17054	Samidurai	60	M	15/02/2019	15/03/2019	30 Days	Fair
19.	33003	Aazath	55	M	06/04/2019	05/05/2019	30 Days	Fair
20.	38353	Alex	37	M	25/04/2019	25/05/2019	30 Days	Fair

BLOOD INVESTIGATION

S. No.	OP No	Before Treatment						After Treatment					
		WBC TC	WBC-DC%			ESR 1 hr	HB	WBC TC	WBC -DC%			ESR 1 hr	HB
			P	L	E				P	L	E		
1.	44662	8100	61	33	6	21	12	6400	62	34	4	18	13
2.	44701	8000	63	30	7	12	13	6800	59	40	1	18	13
3.	45298	8000	60	36	4	15	13.7	7000	64	33	3	18	13.8
4.	47187	7200	61	35	4	15	12.4	8000	55	43	2	12	12.6
5.	50375	7600	64	32	4	20	9.8	7400	62	34	4	18	10
6.	55421	7500	64	27	4	16	10.5	7300	58	30	7	20	10
7.	55935	6800	64	32	4	24	12.6	7200	63	30	7	20	11.8
8.	56318	8000	60	36	4	15	14.3	7600	60	38	2	20	14
9.	58900	9800	64	33	1	15	11.5	8800	68	30	2	18	12
10.	58928	8100	63	33	4	25	13.5	7500	62	35	3	18	12.8
11.	78755	7500	62	32	6	18	14.3	8200	58	40	2	18	14
12.	77895	8100	60	35	5	12	10.5	8600	68	32	-	16	11
13.	104995	8200	63	32	5	15	14	8200	66	28	6	22	13.6
14.	103629	8300	63	35	2	15	11.5	8600	70	30	-	22	11
15.	103830	10410	79	14	7	15	12.3	10100	64	30	6	30	13
16.	105355	8000	66	31	3	17	13	7900	64	32	4	21	13.4
17.	105373	8500	67	25	8	10	11.0	8000	62	38	-	12	11.2
18.	17054	7300	60	37	3	10	11.3	7000	64	32	4	15	11
19.	33003	7200	61	36	3	15	12.3	7800	62	33	5	18	14
20.	38353	8200	64	31	5	11	13.4	8200	62	36	2	24	12

BIOCHEMICAL ANALYSIS

S. NO	OP. NO	Blood Sugar		Blood Urea		Total Cholesterol		Serum creatinine		Bilirubin	
		BFT	AFT	BFT	AFT	BFT	AFT	BFT	AFT	BFT	AFT
1.	44662	93	89	22	20	169	175	0.7	0.4	0.5	0.2
2.	44701	105	102	20	26	209	180	0.9	1.0	0.2	0.4
3.	45298	88	120	26	30	125	143	0.7	0.5	0.5	0.3
4.	47187	96	94	22	18	150	123	0.4	0.2	0.2	0.3
5.	50375	80	96	25	22	216	200	0.6	0.6	0.5	0.2
6	55421	84	102	23	22	146	160	0.6	0.4	0.5	0.2
7.	55935	114	101	16	15	126	138	0.4	0.2	0.2	0.3
8.	56318	67	95	22	18	142	165	0.6	0.5	0.4	0.2
9.	58900	95	102	20	18	148	132	0.4	0.6	0.2	0.4
10.	58928	116	95	22	20	160	129	0.4	0.5	0.2	0.3
11.	78755	102	96	21	18	130	131	0.5	0.4	0.4	0.2
12.	77895	89	104	16	15	128	136	0.5	0.2	0.4	0.3
13.	104995	113	95	16	24	110	142	0.7	0.3	0.5	0.2
14.	103629	116	120	20	18	128	140	1.0	0.9	0.2	0.3
15.	103830	122	102	18	20	139	180	0.7	0.4	0.4	0.5
16.	105355	130	142	16	20	206	178	0.7	0.6	0.2	0.2
17.	105373	97	80	25	23	137	104	0.8	0.5	0.4	0.3
18.	17054	117	128	21	18	166	126	0.8	0.4	0.5	0.3
19.	33003	65	96	26	20	144	126	0.9	0.8	0.5	0.3
20.	38353	96	104	18	22	162	146	0.4	0.2	0.2	0.1

URINE ANALYSIS

S.NO	OP. NO	Before Treatment						After Treatment					
		Alb	**Sugar**	Pus cells	Epi. cells	RBC'S	**casts/crystals**	**Alb**	**Sugar**	**Pus**	**Epi. cells**	**RBC'S**	**casts/crystals**
1.	44662	Nil	Nil	NAD	NAD	NAD	NAD	Nil	Nil	0-1	NAD	NAD	NAD
2.	44701	Nil	Nil	2-4	1-2	NAD	NAD	Nil	Nil	NAD	NAD	NAD	NAD
3.	45298	Nil	Nil	5-7	1-2	NAD	Full of calcium oxalate crystals	Nil	Nil	1-2	0-1	NAD	NAD
4.	47187	Trace	Nil	NAD	NAD	NAD	Full of oxalate crystals	Nil	Nil	NAD	NAD	NAD	NAD
5.	50375	Nil	Nil	2-5	1-2	NAD	NAD	Nil	Nil	0-1	NAD	NAD	NAD
6.	55421	Nil	Nil	5-7	NAD	NAD	NAD	Nil	Nil	0-2	1-2	NAD	NAD
7.	55935	Nil	Nil	0-2	NAD	NAD	NAD	Nil	Nil	NAD	NAD	NAD	NAD
8.	56318	Nil	Nil	1-5	3-4	20-30	NAD	Nil	Nil	NAD	0-1	NAD	NAD
9.	58900	Nil	Nil	5-10	2-3	2-3	NAD	Nil	Nil	NAD	0-1	NAD	NAD
10.	58928	Nil	Nil	2-3	3-5	NAD	NAD	Nil	Nil	NAD	0-2	NAD	NAD
11.	78755	Nil	Nil	NAD	few	few	NAD	Nil	Nil	NAD	0-2	0-1	NAD
12.	77895	Nil	Nil	10-15	NAD	5-10	NAD	Nil	Nil	0-1	NAD	NAD	NAD
13.	104995	Nil	Nil	NAD	1-2	NAD	NAD	Nil	Nil	NAD	NAD	NAD	NAD
14.	103629	Nil	Nil	1-2	NAD	NAD	NAD	Nil	Nil	NAD	NAD	NAD	NAD
15.	103830	Nil	Nil	few	3-5	NAD	NAD	Nil	Nil	0-1	NAD	NAD	NAD
16.	105355	Nil	Nil	few	1-2	NAD	NAD	Nil	Nil	0-1	NAD	NAD	NAD
17.	105373	Nil	Nil	1-2	1-2	NAD	NAD	Nil	Nil	NAD	NAD	NAD	NAD
18.	17054	Nil	Nil	1-2	2-3	NAD	NAD	Nil	Nil	NAD	NAD	NAD	NAD
19.	33003	Nil	Nil	1-2	NAD	2-8	NAD	Nil	Nil	NAD	NAD	NAD	NAD
20.	38353	Nil	Nil	1-2	NAD	1-3	NAD	Nil	Nil	NAD	NAD	NAD	NAD

CASE SHEET OF 20 IN PATIENTS TREATED FOR KALLADAIPPU NOI

S.NO	IP.NO	NAME	AGE	SEX	Starting of treatment	End of treatment	No. of days treated	Result
1.	1600	RajaGopala Moorthy	62	M	21/06/2018	21/07/2018	30	Fair
2.	1765	Avudaiammal	58	F	11/07/2018	10/08/2018	30	Fair
3.	2360	Selvi	50	F	17/09/2018	15/10/2018	29	Good
4.	2393	Mallika	48	F	21/09/2018	20/10/2018	30	Good
5.	2772	Shanthi	53	F	14/11/2018	11/12/2018	28	Fair
6.	5711	Meera	54	F	14/01/2019	13/02/2019	30	Fair
7.	181	Sundari	43	F	28/01/2019	27/02/2019	30	Good
8.	289	Sankarammal	45	F	08/02/2019	07/03/2019	30	Fair
9.	311	Mani	30	M	11/02/2019	13/03/2019	30	Fair
10.	388	Maharasi	48	F	16/02/2019	16/03/2019	30	Good
11.	332	Daisy Rani	52	F	20/02/2019	22/03/2019	30	Good
12.	448	Arumugam	50	F	21/02/2019	23/03/2019	30	Good
13.	591	Pappa	50	F	07/03/2019	06/04/2019	30	Fair
14.	776	Vijayalakshmi	50	F	26/03/2019	25/04/2019	30	Good
15.	836	Subbulakshmi	51	F	01/04/2019	30/04/2019	30	Fair
16.	855	Thamaraivadivu	54	F	02/04/2019	01/05/2019	30	Good
17.	842	Boopathy	60	M	01/04/2019	30/04/2019	30	Fair
18.	918	Tamilselvi	57	F	10/04/2019	10/05/2019	30	Good
19.	1030	Saroja	55	F	25/04/2019	25/05/2019	30	Poor
20.	1187	Shanmugathai	56	F	09/05/2019	25/05/2019	15	Fair

BIOCHEMICAL ANALYSIS

S.NO	IP.NO	Before Treatment							After Treatment						
		WBC TC	WBC-DC%			ESR		Hb%	WBC Total cells/ cub.mm	WBC-DC%			ESR		Hb%
			P	L	E	½ hr	1 hr			P	L	E	½ hr	1 hr	
1.	1600	6600	52	42	6	-	20	13.8	6200	56	40	4	-	17	13.8
2.	1765	7000	63	34	3	-	70	9.4	7600	65	33	2	-	20	10.1
3.	2360	8900	64	33	3	-	12	13.8	8600	61	38	1	-	14	13.6
4.	2393	8300	69	27	4	-	25	8.4	7900	55	43	2	-	18	9
5.	2772	7200	68	31	1	-	20	10.5	7400	66	32	2	-	24	10.8
6.	5711	6100	63	34	3	-	11	10.8	5800	59	36	5	-	12	11.2
7.	181	8200	69	30	1	-	18	11.4	8400	64	30	6	-	19	12.4
8.	289	6500	63	30	7	-	30	10.4	7600	58	38	4	-	16	11
9.	311	7800	71	23	6	-	05	14.2	7900	65	32	3	-	06	14
10.	388	8300	70	23	7	-	110	8.6	8600	62	35	3	-	52	9.5
11.	332	7200	62	34	4	-	51	9.9	7800	65	30	5	-	26	11
12.	448	6400	62	30	8	-	25	9.6	7000	68	31	1	-	18	10.4
13.	591	9600	56	34	10	-	51	12.3	9700	59	37	4	-	20	14.2
14.	776	8100	61	35	4	-	14	11.2	8400	62	37	1	-	12	12.1
15.	836	6900	62	34	4	-	18	10.8	7000	58	34	8	-	16	11.5
16.	855	7300	63	32	5	-	31	10.8	7800	61	35	4	-	18	11
17.	842	6100	65	32	3	-	14	12.4	6700	63	32	5	-	11	13
18.	918	5200	72	25	3	-	34	11	7000	58	40	2	-	28	11.5
19.	1030	5800	58	40	2	-	30	12.4	5900	65	33	2	-	18	11.4
20.	1187	6000	64	32	4	-	12	10	7100	60	32	8	-	17	10.8

BIOCHEMICAL ANALYSIS

S.NO	IP.NO	Blood sugar		Blood urea (mgs %)		Total cholestrol (mgs %)		Serum creatinine		Bilirubin	
		BFT	AFT	BFT	AFT	BFT	AFT	BFT	AFT	BFT	AFT
1.	1600	109	96	30	30	180	162	1.1	1.5	0.5	0.5
2.	1765	176	126	19	32	189	158	0.6	0.9	0.5	0.5
3.	2360	101	104	28	22	189	184	0.9	0.4	0.4	0.4
4.	2393	97	94	20	21	166	165	0.9	0.9	0.5	0.5
5.	2772	95	94	24	16	110	120	0.8	0.8	0.8	0.6
6.	5711	93	193	27	25	193	164	0.9	0.9	0.7	0.7
7.	181	103	104	33	27	182	160	0.4	0.9	0.5	0.4
8.	289	122	128	23	21	126	162	0.5	0.6	0.6	0.6
9.	311	84	96	21	19	168	158	0.7	0.9	0.5	0.5
10	388	80	86	22	16	203	203	0.9	1.4	0.7	0.7
11.	332	108	193	21	22	193	198	1.0	0.8	0.6	0.6
12.	448	116	108	26	26	149	194	0.8	1.4	0.5	0.5
13.	591	93	100	27	18	122	116	0.7	0.5	0.4	0.4
14.	776	98	104	22	15	185	172	1.0	0.8	0.2	0.5
15.	836	106	104	16	20	164	156	0.6	0.7	0.4	0.4
16.	855	96	96	28	20	190	186	0.7	0.7	0.5	0.4
17.	842	100	90	16	20	171	117	0.5	0.8	0.6	0.2
18.	918	125	104	14	18	164	144	0.6	0.7	0.4	0.5
19.	1030	111	120	18	20	182	128	0.9	0.9	0.3	0.5
20.	1187	98	82	12	21	200	161	0.8	0.6	0.7	0.7

URINE ANALYSIS

S.NO	IP. NO	Before Treatment						After Treatment					
		Alb	Sugar	Pus cells	Epi. cells	RBC'S	Casts/ crystals	Alb	Sugar	Pus cells	Epi. cells	RBC'S	Casts/ crystals
1.	1600	Nil	Nil	1-2	1-2	NAD	NAD	Nil	Nil	NAD	NAD	NAD	NAD
2.	1765	+	Nil	15-20	2-4	NAD	NAD	Nil	Nil	NAD	NAD	NAD	NAD
3.	2360	+	Nil	1-4	few	NAD	NAD	Nil	Nil	0-1	NAD	NAD	NAD
4.	2393	Nil	Nil	1-2	0-1	NAD	NAD	Nil	Nil	NAD	NAD	NAD	NAD
5.	2772	Nil	Nil	2-3	2-3	1-2	Few crystals	Nil	Nil	NAD	NAD	NAD	NAD
6.	5711	Nil	Nil	2-5	NAD	1-2	NAD	Nil	Nil	0-1	NAD	NAD	NAD
7.	181	Nil	Nil	1-2	NAD	NAD	NAD	Nil	Nil	0-2	NAD	NAD	NAD
8.	289	Nil	Nil	1-2	NAD	NAD	NAD	Nil	Nil	NAD	NAD	NAD	NAD
9.	311	Nil	Nil	1-2	NAD	NAD	NAD	Nil	Nil	NAD	NAD	NAD	NAD
10.	388	Nil	Nil	2-3	3-10	NAD	NAD	Nil	Nil	NAD	NAD	NAD	NAD
11.	332	Nil	Nil	NAD	NAD	NAD	NAD	Nil	Nil	NAD	NAD	NAD	NAD
12.	448	Nil	Nil	NAD	NAD	NAD	NAD	Nil	Nil	0-1	NAD	NAD	NAD
13.	591	Nil	Nil	4-6	NAD	NAD	NAD	Nil	Nil	NAD	NAD	NAD	NAD
14.	776	Nil	Nil	NAD	0-2	NAD	NAD	Nil	Nil	NAD	NAD	0-1	NAD
15.	836	Nil	Nil	1-2	NAD	3-5	NAD	Nil	Nil	NAD	0-1	NAD	NAD
16.	855	Nil	Nil	1-2	1-2	5-6	NAD	Nil	Nil	NAD	NAD	NAD	NAD
17.	842	Nil	Nil	1-5	NAD	NAD	NAD	Nil	Nil	0-1	NAD	NAD	NAD
18.	918	Nil	Nil	NAD	NAD	NAD	NAD	Nil	Nil	NAD	NAD	NAD	NAD
19.	1030	Nil	Nil	2-5	NAD	NAD	few crystals	Nil	Nil	NAD	0-1	NAD	NAD
20.	1187	Nil	Nil	NAD	0-2	1-2	NAD	Nil	Nil	NAD	NAD	NAD	NAD

CHAPTER-VI
DISCUSSION

My clinical study is "To evaluate the therapeutic efficacy of Open Labelled Phase II Non- Randomized trial drug of ***NERUNJI VER KUDINEER*** (Internal) in the treatment of KALLADAIPPU (Urolithiasis). Out of 20 out patients and 20 in patients were selected based on clinical features and modern investigations parameters and siddha diagnostic methods (Envagai Thervugal) were carried out after the disease.It is confirmed by ultrasonogram. The trial drug ***NERUNJI VER KUDINEER*** was prepared and given to the patients. The blood, urine samples and other general details were collected from the patients before and after treatment. The urolithiasis symptoms score of each patient before and after treatment were compared to assess the therapeutic value of the trail drug ***NERUNJI VER K UDINEER***.

AGE

In this study, among the 20 out-patients, Kalladaippu noi was most common in Pitha Kaalam 34-66 years (70%). and among the 20 in-patients, it was predominant (95%) in Pitha Kaalam 34-66 years.

SEX

From the study, among the 20 outpatients (80%) were Male and (20%) were Female. Whereas among inpatients majority of them were Males (15%) and (85%) were Female cases.

OCCUPATION

From the data collected during the enrollment of patients it was learnt that 40% of the outpatients were Standing workers, and 60% of the inpatients were Housewives.

DIETARY HABITS

Out of the 40 cases who were recruited for the study majority of them (90% of outpatients and 80% of inpatients) were taking both Vegetarian and Non-Vegetarian items.

MARITAL STATUS:

From the data collection, among the 40 patients majority of them (80% of out patients and 95% of in patients) were Married.

PERSONAL HABITS

From the history taken from the patients it was noted that 60% of outpatients and 90% inpatients does not have any Bad Habits. 40% of outpatients and 10% inpatients have Alcoholism, Smoking, Alchohol with Smoking.

PARUVAKAALAM

In General, Kalladaippu Noi occurs in all the seasons. But in the present study, it was found to be the commonest during Ilavenil Kalam (40% outpatients 45% of inpatients) were affected.

THINAI

Among the patients who were selected for the trial 75% of the outpatients and 80% of the inpatients were from Marutha Nilam. 25% of outpatients were from Neithal Nilam, and 20% of inpatients were from Neithal Nilam.

THEGI (CONSTITUTION OF BODY)

In this study,Pitha Thegi patients were found to be the most affected by Kalladippu noi (70% of outpatients and 60% of inpatients), The second major were Vatha Thegi (20% of outpatients and 25% inpatients). Only a few of them (10% of outpatients and 15% of inpatients) were Kabam Thegi.

MANO THATHUVAM (GUNAM)

In this study, Rajo Gunam patients was affected by Kalladaippu noi (75% of out patients and 70% of in patients). The second major were Sathuva Gunam (20% of out patients and 15% of in patients). Only few of them (15% of out patients and 5% of in patients) were Thamo Gunam.

UYIR THATHUKAL

A. DERANGEMENT OF VATHAM

In the contemporary study, it was noted that all the patients under treatment had disturbances in Abaanan , viyanan and Samanan (100%) which was the primary cause for oliguria, dysuria and formation of calculi. Pranan was affected in 15% of outpatients and 10% of inpatients has cold and cough experienced by the patients.

B. DERANGEMENT OF PITHAM

It was noted that Sadhaga Pitham was affected in 80% of outpatients and 60% of inpatients resulting in power to complete the task and difficulty in their regular work in day to day life. Ranjaga Pitham was found to be disturbed in 5% of outpatients and 15% of inpatients. Analagapitham also disturbed in some patients.

C. DERANGEMENT OF KAPAM

Santhigam was found to be affected in 30% of outpatients and 15% of inpatients, causing joint pain in elderly patients. Avalambagam was found to be in 5% of out patients. Kilethagam also affected in 35% of out patients and 25% of in patients.

UDAL THATHUKKAL

Among the patients selected for the study Saaram (100% of out patients and 80% of in patients) was affected causing sluggishness. Enbu Thathu was found to be affected in (50% of out patients and 40% of inpatients) due to joint pain. Senneer was found to be affected in 20% of outpatients and 15% of inpatients.

KOSANGAL

Among the 40 patients, Annamayakosam (85%) was affected in all patients due to Udal Thathukal. Pranamayakosam was affected in (20% of out patients and 15% of in patients) due to Pranan i.e cold and cough.

14 VEGANGAL

Among the 40 cases, controlling of Siruneer (100%) was affected in all patients leads to Oliguria, Dysuria and Haematuria. Controlling of Nithirai was affected in few cases (30% of out patients and 35% of in patients) leads to Oliguria.

ENVAGAI THAERVUGAL

In this study, Moothiram (100%) was affected in all the patients. Pitha Vatha Naadi was felt in most of the patients (60% of outpatients and 55% of inpatients).The second major type of Naadi was Vatha Pitha Naadi (35% of outpatients and 25% of inpatients).It was noticed that only 5% of the outpatients 20% of the inpatients had Vatha Kabha Naadi. Sparism was affected in 25% of out patients and 35% of in patients.

NEERKURI

It was noted that the urine colour was Yellowish (60% of outpatients and 70% inpatients) and Yellowish Red in (20% of out patients and 5% of in patients), it was normal in 10% of outpatients and 25% of inpatients. Nurai normal in all the patients. Edai was affected in all the 40 patients (100%) due to Haematuria, Dysuria, and mixed with Calculus. Maanam was affected in all the patients (100%) due to Fleshy, Charred ,Ketotic Odour. Enjal was affected in (80% of out patients and 85% of in patients) due to Oliguria, Haematuria.

NEIKURI

When Neikuri was tested in the urine samples of the patients it was observed that majority of them (65% of outpatients and 75% of inpatients) revealed that Pitha Neer. (20% of outpatients and 15% of inpatients) were Vatha Neer. (15% of out patients and 10% of in patients) were Kapha Neer.

DURATION OF ILLNESS

Majority of the patients experienced symptoms of Kalladaippu noi only in the past less than 8 weeks (85% of outpatients and 90% of inpatients) and 2-6 months (10% of outpatients and 10% of inpatients). (5% of outpatients) suffered from the disease from 6 month – 1 year.

NUMBER OF STONES

Before treatment majority of them have Single Stone (50% of out patients and 55% of in patients), and Multiple Stones (50% of out patients and 45% of in patients). But after treatment (15% of out patients and 20% of in patients) have Single stone (Reducing in size of the stone) and Multiple Stones (20% of out patients and in patients) were affected.

POSITION OF STONES

The USG reports of the patients have stones which were mostly (45% of outpatients and 50% of inpatients) present in Left Kidney. In Right Kidney calculi were comparatively lesser (35% in outpatients and 40% in inpatients) and (10% of outpatients and 10% of inpatients) had stones in Both Kidneys. In Left Ureter (5% of out patients and 5% of in right ureter.

SIZE OF STONES

The USG reports of the cases before treatment showed that majority of the cases (60% of the outpatients and 20% of the inpatients) presented with stone of size 5mm and above. And 4-5mm (10% of out patients and 40% of in patients). And 1-3mm (30% of out patients and 25% in patients) were affected. After treatment (35% of out patients and 35% of in patients) have normal study report and have no symptoms. Thus the Statistics Analysis also considered as SIGNIFICANT $P<0.0001$.

UROLITHIASIS SYMPTOMS SCORE

From the above study, Before treatment the patients (25% of out patients and 35% of in patients) were Severely affected. And (60% of out patients and 65% in patients) were Moderately affected. After treatment most of the patients (15% of out patients and 20% of in patients) have No Symptoms that is Normal Study and

also Relief in Symptoms. And (15% of out patients) have Mild scores. And also (15% of out patients and 20% of in patients) have Moderately affected (reducing in stone size and relief in symptoms). Thus the Analysis also considered as ***SIGNIFICANT P<0.0001.***

GRADING OUTCOME OF THE STUDY

The trail medicine selected for the clinical study was *NERUNJI VER KUDINEER - 100ml* BD Morning & Evening . The present study proved the therapeutic values of the trial medicine which is evident from the Absence of Calculi and Symptoms associated with Kalladaippu Noi in majority of the patients. *Good response was noticed in (75% of outpatients and 50% of inpatients) and Moderate response in (25% of outpatients and 45% of inpatients). The good and moderate response of trial drug in treating Kalladaippu noi is attributed to the lithotriptic, diuretic and analgesic effects of the trial medicine*.

STATISTICAL ANALYSIS :

Statistical Analysis of the Size of Stone :

The mean value of size of the stone (mm) before and after treatment was respectively 6.5375 & 2.7750 and the standard deviation was 5.45540 & 3.60190.Pearson correlation (r) before and after treatment among in patients size of stone is 0.856. P- value followed to be less than 0.0001 is considered to be extremely statistically significant. There is strong evidence (t= 4.873, P< 0.0001) that the clinical trial drug importance the Kalladaippu patients. In this data set we could get a mean paired difference, df =39, with the confidence interval of 95% the null hypothesis is rejected, since P<0.0001.

Statistical analysis of the Urolithiasis Symptom Score :

The mean value of Urolithiasis Symptom Score before and after treatment was respectively 12.4000 & 1.7250 and the standard deviation was 4.17440 & 3.55894. Pearson correlation (r) before and after treatment of Urolithiasis Symptom Score among in patients is -0.196. P- value followed to be less than 0.0001 is considered to be extremely statistically significant. There is strong evidence (t=3.065, P< 0.0001) that the clinical trial drug importance the Kalladaippu patients. In this data set we could get a mean paired difference, df =39, with the confidence interval of 95% the null hypothesis is rejected, since P<0.0001.

CHAPTER-VII
SUMMARY

- The aim of the study is to Evaluate the therapeutic efficacy of the drug ***NERUNJI VER KUDINEER*** in ***KALLADAIPPU.***
- Before intiating the clinical trial, got approval from INSTITUTIONAL ETHICAL COMMITTEE (IEC) in Government Siddha Medical College. Palayamkottai. Tirunelveli. And got approval from INSTITUTIONAL ANIMAL ETHICAL COMMITTEE (IAEC) at K.M.COLLEGE OF PHARMACY, MADURAI.
- The drugs were authenticated, and also done Biochemical Analysis in Govt. Siddha Medical College, Palayamkottai. Tirunelveli.
- The drug undergo Pharmacological Study has done at K.M. College of Pharmacy, Madurai. Microbial study also done at Inbiotics at Nagercoil.
- For clinical study, among 40 cases were selected and recruited for the clinical trial, clinical diagnosis made by both Siddha and modern methodology.
- Before initiating the trial informed consent was obtained from the patients.
- All the patients were treated for a period of 30 days. The trial medicine selected for internal treatment was ***NERUNJI VER KUDINEER*** at the dose of 100ml twice a day referred under Siddha literature ***ATHMARATCHAMIRTHAM ENNUM VAIDHYA SARASANGIRAGAM,*** Page.no.349.
- Required laboratory investigations were carried out before and after treatment and the concerned data was recorded in the proforma.
- Clinical assessment was done during each visit in OPD Patients (2 days once) and the data was noted in the prescribed proforma.
- During the study period there was no event of any adverse reactions owing to the drug and disease.
- The patients were showed good prognosis within a short period, Oliguria and Burning Micturation reduced within 7 days of treatment.
- It is observed that all other signs and symptoms relived at the end of course of treatment with the trial medicine and strict diet restriction.

- From the clinical examination and enquiring the patients, it was noted that stones were broken into fragments and expelled out in the form of sand grains and travels with urine. It is evident from the ultrasonographic investigations that the trial medicine helped in disintegrate of the calculus in some patients.
- Statistical Analysis of Urolithiasis Symptoms Score also shows significant $P<0.0001$.
- Among 40 cases, Good response was noticed in 75% of OPD and 50% of IPD. And Moderate response in 25% of OPD and 45% of IPD. Poor response in 5% of IPD.
- In this study, it has been proved that the trial medicine, ***NERUNJI VER KUDINEER*** (*Internal*) is highly effective and economically viable in curing ***KALLADAIPPU NOI***.

CHAPTER VIII

CONCLUSION

The following conclusions have been drawn from the A Prospective Open Labelled Phase II Non- Randomized Clinical Trial on "The evaluation of efficacy of the drug, **(internal)** in ***NERUNJI VER KUDINEER*** treating ***KALLADAIPPU NOI*** was carried out at the PG Department of Pothu Maruthuvam, Government Siddha Medical College and Hospital, Palayamkottai as my dissertation work.

1. The Ingredients incorporated in the trial medicine helped to cure Kalladaippu Noi by compensating the increased Pitham which is attributed to the **Diuretic, Lithotriptic action, Analgesic** effect, as mentioned in the various Siddha Literatures.
2. The Biochemical Analysis of trial medicine revealed that the presence of various minerals like **Calcium, Sulphate, Chloride, Ferrous Iron and Unsaturated Compounds .**
3. The Pharmacological Study on trial medicine was confirmed the Lithotriptic, diuretic and analgesic effect of the medicine.
4. The Microbial Analysis showed a very sensitive to my trial drug of ***NERUNJI VER KUDINEER*** of *Staphylococcus aureus, Streptococcus mutans ,Bacillus subtilis and E.coli.*
5. The Ultra Sonogram Reports of some patients Before treatment and After treatment were compared to evaluate the prognosis in patients.
6. Clinically, the trial medicine is free from side effects as no patient experienced side effects during the course of treatment.
7. The result showed Good Response in 75% of OPD and 50% of IPD and Moderate Response in 25% of OPD and 50% of IPD.

The Medicine was found to have *Lithotriptic, Diuretic, Analgesic* effect, and have properties to compensate the increased Pitham, which is one of the important causes for Kalladaippu Noi. From this study, it has been proved that the trial medicine of **NERUNJI *VER KUDINEER*** is highly effective in curing ***KALLADAIPPU NOI.***

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GOVERNMENT SIDDHA MEDICAL COLLEGE,

PALAYAMKOTTAI

SCREENING COMMITTEE

Name of the candidate :Dr.P.Bernath

Candidate Reg No : _____

Department : **Pothu Maruthuvam**

This is to certify that the dissertation topic an open clinical study to evaluate the efficacy of Siddha Sashtric Formulation.

"NERUNJI VER KUDINEER" for the treatment of KALLADAIPPU [UROLITHIASIS] has been approved by the screening committee.

Branch	Department	Name	Signature
I	Pothu Maruthuvam	Prof. Dr. A. Manoharan MD (S)	26/5/17
II	Gunapadam	Dr. A. Kingsly MD (S)	26/5/17
III	Sirappu Maruthuvam	Dr. A. S. Poongodikanthimathi MD (S)	26/5/17
IV	Kuzhanthai Maruthvam	Prof. Dr. D. K. Soundararajan MD (S)	26/5/17
V	Noi Nadal	Prof. Dr. S. Victoria MD (S)	for 26/5/17
VI	Nanji Nool Maruthuvam	Prof. Dr. M. Thiruthani MD (S)	For 26/5/17

Place: Palayamkottai

Date:26.05.2017

26/5/17

PRINCIPAL
Govt. Siddha Medical College
Palayamkottai.

INSTITUTIONAL ETHICAL COMMITTEE,
GOVERNMENT SIDDHA MEDICAL COLLEGE,
PALAYAMKOTTAI, TIRUNELVELI- 627002,
TAMIL NADU, INDIA.

Ph: 0462-2572736/2572737/2582010 Fax: 0462-2582010

Email ID: gsmc.palayamkottai@gmail.com

R.No.GSMC/5676/P&D/Res/IEC/2014Date: 29.05.2017

CERTIFICATE OF APPROVAL

Address of Ethical Committee	Government Siddha Medical College, Palayamkottai-627002, Tirunelveli district.
Principal Investigator	Dr.P.Bernath,MD(s), First year, Department of Pothu Maruthuvam, Reg. No: Not yet registered.
Supervisor	**Prof.Dr.A.Manoharan, M.D(s).,** Head of the Department, Department of Pothu Maruthuvam, Government Siddha Medical College and Hospital, Palayamkottai - 627002, Tirunelveli District. drmanoharan25@gmail.com
Guide	**Dr.S.Justus Antony, M.D(s)** Lecturer Greade II, Department of Pothu Maruthuvam Government Siddha Medical College and Hospital, Palayamkottai - 627002, Tirunelveli District. Justusantony71@gmail.com
Dissertation Topic	AProspective open labelledNon Randomized Clinical trial on herbal formulation of **"*Nerunji Ver Kudineer*"** for the treatment of **KALLADAIPPU(Urolithiasis)**
Documents Filed	(1)Protocol (2)Data Collection Forms (3)Patient Information Sheet (4)Consent Form (5)SAE (Pharmacovigilance)
Clinical/Non Clinical Trial Protocol (Others-Specify)	Clinical Trial Protocol-yes
Informed Consent Document	Yes
Any other Document	Case Sheet/Investigation Documents
Date of IEC Approval & its Number	29.05.2017 , GSMC-IV-IEC/2017 Br-I-02/29.05.2017

We approve the trial to be conducted in its presented form.

The Institutional Ethical Committee expects to be informed about the process report to be submitted to the IEC at least annually of the study, any SAE occurring in the course of the study, any changes in the protocol and submission of final report.

Chairman

Prof. Dr. M.Murugesan M.D(S)

Member Secretary

29/5/17

Prof.Dr.R.Neelavathy M.D(S) Ph.D

K.M. COLLEGE OF PHARMACY – MADURAI

IAEC – CERTIFICATE

This is to certificate that the project title AN OPEN NON-RANDOMIZED CLINICAL TRIAL ON **"KALLADAIPPU" (UROLITHIASIS)** USING THE SIDDHA DRUG **"NERUNJI VER KUDINEER"** AS INTERNAL MEDICINE has been approved by the **IAEC/P. BERNATH /TNMGRMU/MD(S)/ 321611002/ KMCP/ 24/2018.**

Dr. N. CHIDAMBARANATHAN

Name of the Chairman / Member Secretary IAEC:

Dr. P. THIRUPATHY KUMARESAN

Name of the CPCSEA Nominee

Signature with Date 11/5/18

I. A. E. C. CHAIRMAN
INSTITUTIONAL ANIMAL ETHICAL COMMITTEE
K. M. COLLEGE OF PHARMACY
MADURAI-625 107.

11/5/18

CPCSEA NOMINEE
INSTITUTIONAL ANIMAL ETHICS COMMITTEE
K M. COLLEGE OF PHARMACY
MADURAI-625 107

Chairman / Member Secretary of IAEC

CPCSEA Nominee

(Kindly make sure that minutes of the meeting duly signed by all the participants are maintained by office).

Clinical Trial Details (PDF Generation Date :- Wed, 03 Jul 2019 07:24:42 GMT)

CTRI Number	CTRI/2018/03/012710 [Registered on: 21/03/2018] - Trial Registered Prospectively
Last Modified On	21/03/2018
Post Graduate Thesis	Yes
Type of Trial	Interventional
Type of Study	Siddha
Study Design	Single Arm Trial
Public Title of Study	A clinical study NERUNJI VER KUDINEER for KALLADAIPPU [Urolithiasis]
Scientific Title of Study	A Prospective Open Labelled Non Randomized Clinical Trial on herbal formulation of NERUNJI VER KUDINEER for the treatment of KALLADAIPPU[Urolithiasis]

Secondary ID	Identifier
NIL	NIL

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Bernath P
Designation	PG Student
Affiliation	Govt Siddha Medical College And Hospital
Address	PG Second year Department of Pothu Maruthuvam Govt Siddha Medical College And Hospital Palayamkottai Tirunelveli TAMIL NADU 627002 India
Phone	9486805805
Fax	
Email	dr.a.bernath@gmail.com

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Prof Dr A Manoharan MD
Designation	Head Of Department Department of Pothu Maruthuvam
Affiliation	Govt Siddha Medical College And Hospital
Address	Head Of Department Department of Pothu Maruthuvam Govt Siddha Medical College And Hospital Palayamkottai Tirunelveli TAMIL NADU 627002 India
Phone	9443886700
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Email	drmanoharan25@gmail.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Prof Dr A Manoharan MD
Designation	Head Of Department Department of Pothu Maruthuvam
Affiliation	Govt Siddha Medical College And Hospital
Address	Head Of Department Department of Pothu Maruthuvam Govt Siddha Medical College And Hospital Palayamkottai Tirunelveli TAMIL NADU 627002 India
Phone	9443886700

GOVERNMENT SIDDHA MEDICAL COLLEGE

PALAYAMKOTTAI

Certificate of Botanical Authenticity

Certified the following plant drug used in Siddha formulation (Internal) **"NERUNJI VER KUDINEER"** for **KALLADAIPPU** (UROLITHIASIS) taken up for Post-Graduation Dissertation Studies by Dr.P,BERNATH PG Scholar MD siddha, Department of Pothu Maruthuvam, are correctly identified and authenticated through Visual inspection / Organoleptic Characters / Experience, Education & Training Morphology Microscopically and Taxonomical methods.

Table 1: Ingredients of Nerunji ver kudineer

S.N	Drug	Botanical Name	Family	Parts Used
01	Nerunji ver	*Tribulus terrestris.Linn*	Zygophyllaceae	Root
02	Sirupeelai ver	*Aerva lanata.Linn*	Amaranthaceae	Root
03	Sirukeerai ver	*Amaranthus tricolor.Linn*	Amaranthaceae	Root
04	Seeragam	*Cuminum cyminum.Linn*	Apiaceae	Fruit

Station: Palayamkottai

Date : 12.2.2018

12/2/18

Authorized Signature

Dr. S. SUTHA, M.Sc.,M.Ed.,Ph.D.,
Associate Professor
Dept. of Medicinal Botany
Govt. Siddha Medical College
Palayamkottai, Tirunelveli - 2.

BARANI SCANS
Serving with Humanity
Registered with AERB, Lab Accredited by CMC Vellore

Name	Mr. SIVA KUMAR	21.09.2018
Age/ Sex	36 Y/M	174 /USG

USG ABDOMEN

Thanks for reference

Liver

Liver parenchyma shows normal size, and morphology. Diffuse parenchymal hyperechogenicities is seen in liver. No evidence of focal lesion is seen. IHBR are not dilated. Portal vein and its major branches appear normal.

GB:

Gall bladder appears normal. No abnormal echogenecity or evidence of calculus seen. CBD is not dilated.

Pancreas

Pancreatic parenchyma appears normal. Pancreatic duct is not dilated. No evidence of calcification or abnormal echogenecity is seen.

Spleen:

Parenchyma appears normal in size and echogenecity. No evidence of focal lesion is seen.

KIDNEYS:

Right kidney measures 9.8x4.5cms. Left kidney measures 9.4x4.8cms. Parenchymal echoes are normal. CMD is maintained. Pelvicalcyceal system of left kidney is dilated. Left ureter is dilated. There is a calculus measuring 7mms present in left lower ureter. Pelvicalcyceal system of right kidney is not dilated. Right ureter is not dilated. There is a calculus measuring about 10mms present in upper pole of right kidney. There is a cyst measuring about 2.4x2.4cms present in upper pole of right kidney.

Urinary Bladder:

Bladder appears normal. No evidence of calculus is seen. No significant wall thickening is seen.

Prostate:

Prostate is normal in size (13ccs) and echogenecity.
Retroperitoneal structures appear normal.
No significant inflammatory changes or mass in RIF.
No significant free fluid in abdomen and pelvis.

IMPRESSION:

- **Mild diffuse fatty changes in liver**
- **Right renal cortical cyst with Non obstructing right renal calculus.**
- **Left lower ureteric calculus (about 7mms) causing obstruction and mild left hydroureteronephrosis.**
- **Normal sonographic study of GB, pancreas, spleen, bladder and prostate.**

Note: This imaging modality has its own limitations. Hence it should be correlated with clinical and other parameters.
Patient's identity is not verified.

Dr. R.GUNASEELARAJAN DMRD
CONSULTANT RADIOLOGIST
Ph.No: 9443555342

9-B, Thiruchendur Road, (Near Murugankuruchi Signal)
Palayamkottai, TIRUNELVELI - 627 002. Ph : 0462 - 2583222 email : baraniscans@yahoo.com

Name	MR.SIVAKUMAR.R	Patient ID	AS_VPI_US_15968
Accession No	16_015968_192267	Age/Gender	36Y / Male MS
Referred By	Dr.GOVT.SIDDHA MEDICAL COLLEGE	Date	22/10/2018

USG REPORT - ABDOMEN AND PELVIS

LIVER:
Is normal in size and uniform echo texture.
No obvious focal lesion seen. No intra – Hepatic billiary radical dilatation seen.

GALL BLADDER:
Is adequately distended. No calculus or internal echoes are seen.
Wall thickness is normal. The CBD is not dilated.

PANCREAS:
Appears normal in size and shows uniform echo texture.

SPLEEN:
Appears normal in size and it shows uniform echo texture.

KIDNEYS:

Right kidney measures 9.9 x 4.6cms.
A calculus of size 4mm seen in mid calyx of right kidney.
A cortical cyst of size 2.9 x 2.1cms seen in mid pole of right kidney.
Left kidney measures 9.2 x 5.0cms.
Cortico medullary differentiation is within normal.
No evidence of pelvicalyceal dilatation.

BLADDER:
Is normal in contour. No intraluminal echoes are seen. No calculus or diverticulum is seen.

PROSTATE:
Measures 4.0 x 2.8 x 2.7cms. Vol: 16.4cc.

RIF:
Appear normal. No free fluid.

IMPRESSION:

- **Right renal calculus.**
- **Right renal cortical cyst.**

DR. K.MANOHARAN, MD, DMRD.,
CONSULTANT RADIOLOGIST.

Note : This imaging modality is having its own limitations. Hence this report should be correlated with clinical features and other parameters.

Genesys Diagnostic Centre
94870 90622 | 99443 89166
PNDT Reg.No.PNA / 2675 / TNV / 17

NAME	Mr. JOSEPH	AGE	28 / M
REF. BY	Dr.GILBERT SJS., MS.,	DATE	11.12.2018
CLINICAL DIAGNOSIS		REG.NO	F 04025

Thank you for your referral

USG ABDOMEN

Liver	:	Normal in size and echotexture. Portal vein normal in caliber. No IHBR dilatation.
GB	:	No calculus seen. No GB wall thickening seen.
Spleen	:	Normal in size, measures 10.9 cm and echotexture.
Pancreas	:	Normal in size and echotexture.
Right Kidney	:	Normal in size and measures 12.6 x 5.6 cm. Cortical echoes normal. Cortico medullary differentiation is maintained **Calculus seen measuring 10 mm in lower calyx and calculus seen measures 9 mm interpolar calyx.** **Moderate right hydroureteronephrosis noted .Right lower ureteric calculus seen measures 9.2 mm (2 cm distal to iliac vessel crossing)**
Left Kidney	:	Normal in size and measures 11 x 5.1 cm. Cortical echoes normal. Cortico medullary differentiation is maintained No pelvicalyceal system dilatation. **Calculus seen measuring 5 mm in interpolar calyx. and calculus seen measures 4 mm upper pole.**
Bladder	:	Normally distended. No calculus seen. No wall thickening seen.
Prostate	:	Measures 3.5 x 3.5 x 3 cm. (Volume 19.9 cc). Normal in size and echotexture.
RIF	:	No focal mass or abscess. No free fluid. No paraaortic lymphadenopathy.

IMPRESSION:

- ***Right lower ureteric calculus causing moderate hydroureteronephrosis.***
- ***Bilateral renal calculi.***
- ***Normal study of liver, GB, spleen, pancreas, bladder and prostate.***

DR.T.PRINCE JEBA ANAND., MD(RD).,
CONSULTANT RADIOLOGIST

This report is a professional opinion based on the ultrasound images and the available clinical information. If there is any clinico- radiological disparity. Kindly give your valuable feedback with additional clinical details for a free re examination of the patient

Name: MR. JOSEPH	DATE :12/01/2019 AGE/ SEX: 28 /M
Ref. Dr. : Dr. Govt Siddha Medical	

USG - ABDOMEN

Liver	Liver is normal in size 12.8 with uniform echotexture. No focal alteration in echotexture. intrahepatic biliary radicles appear normal. Common duct appears normal. Portal and hepatic veins appear normal.
Gall Bladder	Gall bladder is adequately distended. No abnormal intraluminal echoes. Commonduct appeared normal. No calculi seen in the commonduct.
Spleen	Spleen appeared normal size 8.6cm
Pancreas	Pancreas appeared normal
Aorta	Aorta appeared normal. No para aortic nodes seen.
Right kidney	Right kidney measures10.0X4.5cm. **Non obstructing calculi measuring ~ 7 mm noted in the interpolar region of right kidney. Mild proximal right hydroureteronephrosis.**
Left kidney	Left kidney measures 9.9X5.3 cm. **Small non obstructing calculi measuring 3mm noted in lower pole of left kidney.** Cortex and collecting system of left kidney appears normal.
Urinary bladder	Bladder appeared minimally distended. Both VUJ appears normal.
Prostate	Prostate normal in size and measures 2.5 X 2.9 X 3.1cmVol:12ml.

BHARAT SCANS
Innovation at work

Name: MR. JOSEPH	DATE :12/01/2019 AGE/ SEX: 28 /M
Ref. Dr. : Dr. Govt Siddha Medical	

IMPRESSION:

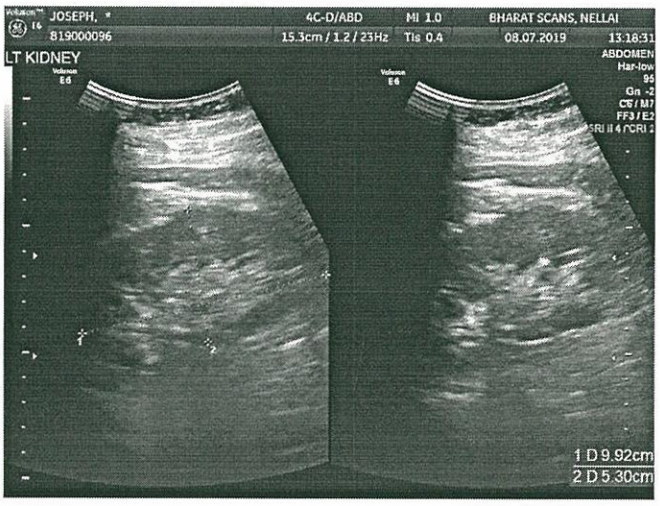
- **Mild right hydroureteronephrosis in proximal ureter.--- suggested clinical correlation/further evaluation.**
- **Bilateral renal calculi**

- **Normal sonographic study of Liver, Gall bladder, Spleen , Pancreas, Urinary bladder and Prostate.**

DR SM MOHIDEEN FATHIMA MD,RD.,
CONSULTANT RADIOLOGIST

BHARAT SCANS
Innovation at work

Patient name	MR JOSEPH	Age/Sex	28 Years / Male
Patient ID	819000096	Visit No	1
Referred by	Dr. GOVERMENT HOSPITAL	Visit Date	12/01/2019 01:10:00 PM



Quality is our Image

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Vanuvampet, Chennai-91
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ASHOK NAGAR
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Ph : 044 44 200 200 / 98410 46663

TIRUNELVELI
110, Narth Bye Pass Road,
Vannarpettai, Tirunelveli-03.
Ph : 95516 90005 / 72990 70009

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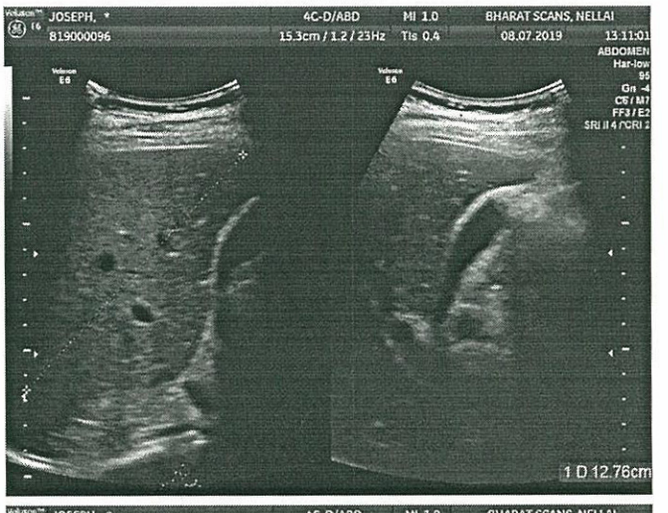
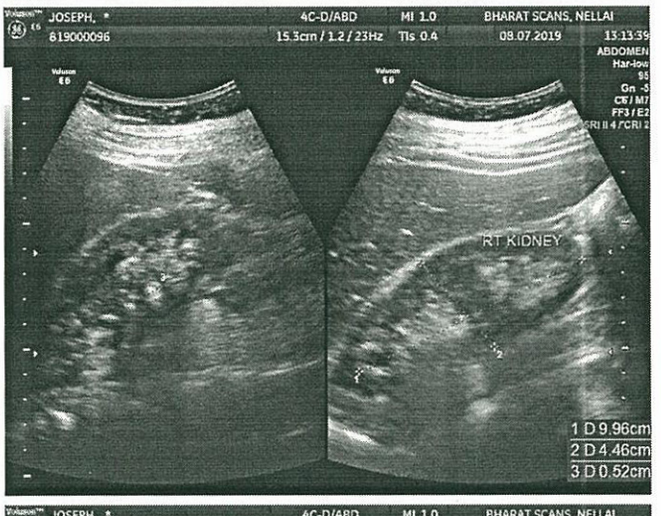
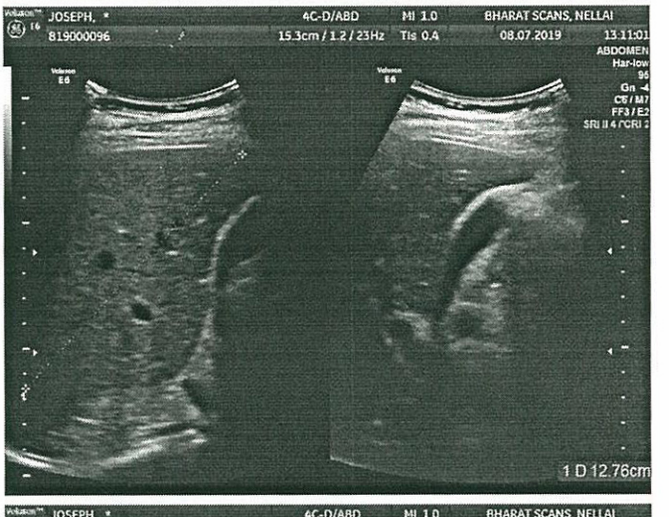
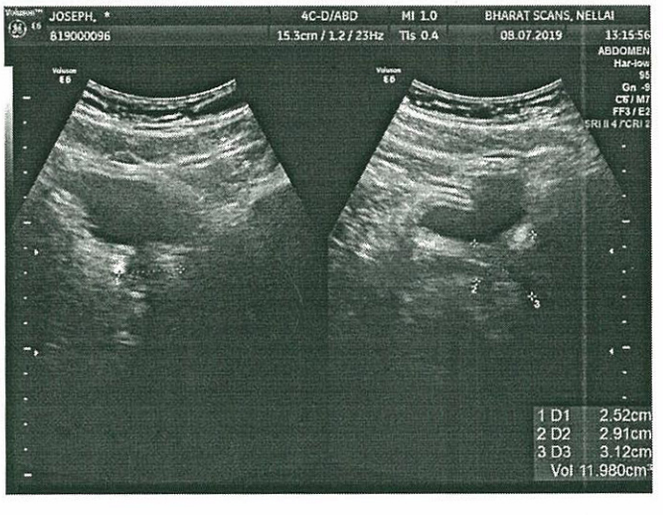
Patient name	MR JOSEPH	Age/Sex	28 Years / Male
Patient ID	819000096	Visit No	1
Referred by	Dr. GOVERMENT HOSPITAL	Visit Date	12/01/2019 01:10:00 PM









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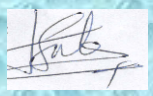

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